

**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 Madhulika Gupta
 SIGNATURE M Gupta
 DEPARTMENT Pediatrics
 ADDRESS AS-136 VRL
 PHONE NUMBER X 55099
 EMERGENCY PHONE NUMBER(S) 519-472-9515
 EMAIL mbgupta@uwo.ca

Location of experimental work to be carried out: Building(s) VRL Room(s) AS Bench AS-116(etc)

*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: NSERC CIHR Human Growth Foundation
 GRANT TITLE(S): Identif. of Biomarkers for Fetal Growth Restriction
2) Role of IGFBP-1 phosphorylation in fetal growth

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:
 1. Maxim Seferovic 3. Majida Abu shehab (Part-time)
 2. Joseph Dube 4. Delilah O Banko (Part time)
Steve Dixon*

In the absence of PI, please contact Steve Dixon, Sr Technician

1.0 Microorganisms

1.1 Does your work involve the use of biological agents? 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? 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
	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No			<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 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? 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	<input checked="" type="radio"/> Yes <input checked="" type="radio"/> No		Not applicable
Rodent	<input type="radio"/> Yes <input type="radio"/> No		
Non-human primate	<input type="radio"/> Yes <input type="radio"/> No		
Other (specify)	<input type="radio"/> Yes <input type="radio"/> 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	<input checked="" type="radio"/> Yes <input type="radio"/> No	HepG2	ATCC
Rodent	<input type="radio"/> Yes <input type="radio"/> No		
Non-human primate	<input type="radio"/> Yes <input type="radio"/> No		
Other (specify)	<input type="radio"/> Yes <input type="radio"/> 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 type(s) indicate PHAC or CFIA containment level required 1 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		<input checked="" type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown	<i>pl - see email attached</i>	<input type="radio"/> 1 <input checked="" type="radio"/> 2 <input type="radio"/> 3
Human Blood (fraction) or other Body Fluid		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown		<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3
Human Organs or Tissues (unpreserved)		<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown		<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 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

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

4.3 Will genetic modification(s) 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

* 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: _____

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

7.0 Use of Animal species with Zoonotic Hazards

N/A

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

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

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 Requiring CFIA Permits

N/A

9.1 Do you use insects that require a permit from the CFIA? 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:

9.7 Please attach the CFIA permit.

9.8 Please describe any CFIA permit conditions:

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

10.0 Plants Requiring CFIA Permits

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

10.9 Please describe any CFIA permit conditions:

11.0 Import Requirements *N/A*

11.1 Will any of the above agents be imported? YES, please give country of origin _____
If no, please proceed to Section 12.0 NO

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 biohazardous agents in Sections 1.0 to 9.0 have been trained.

SIGNATURE MB Gupta

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.

01 02 03

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

VRL AS-116
Certified on
Aug. 7, 2008
Maile Ryden

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 M B Gupta Date: Nov. 10, 2009

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 For the use of amniotic fluid and plasma samples (level 2 certified lab and the ~~fume hood~~ when needed following Health Canada's laboratory biosafety guidelines for handling infectious substances (Chapter 3). My students have obtained training for the use of these samples. The students also use personal protective equipment. These measures provide any incidences /events that could lead to an infection such as spills, splashes and centrifuge accidents or any aerosol exposure during performing laboratory procedures. As a result we prevent risks associated with inhalation, ingestion, mucous membrane contact, etc.

biological safety cabinet

15.0 Approvals

UWO Biohazard Subcommittee: SIGNATURE: _____ Date: _____

Safety Officer for Institution where experiments will take place: SIGNATURE: Maile Ryden Date: November 30, 2009

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:

Gupta, M. /CV/Jan 31, 2007

Appendix 1

Page 1 of 1

Current and Future Research

My research program involves strategies to understand the molecular mechanisms associated with human fetal growth restriction (FGR) and in parallel to identify biomarkers for prediction/diagnosis of the disease. My research can be subdivided into two major areas using a targeted and a global approach and, although each is unique in itself, they both possess complementary overlap which allows for an enhanced understanding of the overall pathophysiology of the disease.

Targeted approach**1. To study the clinical and functional roles of two specific proteins involved in FGR**

Combining traditional biochemical and modern proteomic technology, the focus of my research is to conduct these studies using (a) human cell culture model (hepatic HepG2) and also (b) human clinical samples from normal and FGR pregnancies (Maternal and fetal plasma and amniotic fluid).

A. IGFBP-1 (Phosphorylation)

To determine the status and the functional role of IGFBP-1 phosphorylation in modulation of IGF-1 bioactivity under specific conditions associated with FGR. This study will be extended further to identify and characterize the kinases and the metabolic pathways involved in the process.

B. Haptoglobin expression (Glycosylation)

To investigate the regulatory and potential glycosylation changes in hepatic and decidual hp and lay the foundation towards uncovering biochemical processes related to growth restricted pregnancies.

Global approach**A. Proteomic profiling to identify proteins unique to human FGR**

- a. To elucidate the maternal plasma proteome to discover proteins that are unique to the disease. This study will be extended by establishing the function of the identified proteins, and the potential molecular pathways that may be linked with FGR.
- b. To apply a quantitative mass spectrometric proteomic method to a range of biological and physiological conditions to draw valuable conclusions for both biomarker discovery and for mechanistic studies.

Significance of research

My research will contribute greatly to our understanding of the molecular basis of FGR. Furthermore the application of novel proteomic techniques hold promise for the identification of potential biomarkers for early prognosis and or diagnosis and in management of the disease. The outcomes of this research will allow formulating further mechanistic studies that are critical for therapeutic and preventative interventions for FGR.

Cell Biology

ATCC® Number: **HB-8065™** Order this Item Price: **\$264.00**

Designations: **Hep G2**

Depositors: **Wistar Institute**

Biosafety Level: **1**

Shipped: **frozen**

Medium & Serum: **See Propagation**

Growth Properties: **adherent**

Organism: ***Homo sapiens* (human)
epithelial**

Morphology:



Source:

Organ: liver

Disease: hepatocellular carcinoma

alpha-fetoprotein (alpha fetoprotein); albumin; alpha2 macroglobulin (alpha-2-macroglobulin); alpha1 antitrypsin (alpha-1-antitrypsin); transferrin; alpha1 antichymotrypsin; (alpha-1-antichymotrypsin); haptoglobin; ceruloplasmin; plasminogen; [3525]

Cellular Products:

complement (C4); C3 activator; fibrinogen; alpha1 acid glycoprotein (alpha-1 acid glycoprotein); alpha2 HS glycoprotein (alpha-2-HS-glycoprotein); beta lipoprotein (beta-lipoprotein); retinol binding protein (retinol-binding protein) [3525]

In addition to the MIA mentioned above, other ATCC and/or regulatory permits may be required for the transfer of this ATCC material. Anyone purchasing ATCC material is ultimately responsible for obtaining the permits. Please click here for information regarding the specific requirements for shipment to your location.

Permits/Forms:

Applications:

transfection host (Nucleofection technology from Lonza Roche FuGENE® Transfection Reagents)

Receptors:

insulin; insulin-like growth factor II (IGF II) [22446]

Tumorigenic:

No

DNA Profile (STR):

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----- Original Message -----

Subject:Re: Biohazardous Agents Registry Form: Gupta

Date:Tue, 01 Dec 2009 09:59:05 -0500

From:Jennifer Stanley <jstanle2@uwo.ca>

To:mbgupta@uwo.ca

CC:m Gail Ryder <Gail.Ryder@LawsonResearch.Com>

References:<4B143CEC.4090404@uwo.ca>

<0KTY00KOX1N7Q830@zeppo.mail.uwo.pri>

Hi Dr. Gupta

Ok- but can you clarify question 3 - do you use a biological safety cabinet or a fume hood?

For details, you may want to check out Chapter 9 of the Laboratory Biosafety Guidelines:

<http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index-eng.php>

Regards

Jennifer

mbgupta@uwo.ca wrote:

> Hi Jennfer,

> I am sorry I misunderstood this aspect. There is no infectious agent

> what so ever used in my research. Please make this correction in my

> form. I am using blood from health mothers and the women with

possible

> fetal growth restriction that is all.

> This is the reason it is not in my research summary. Please let me

> know how I could get this rectified.

> Thanks,

> Madhulika

>

>

>>

Subject: Re: Biohazardous Agents Registry Form: Gupta
From: Jennifer Stanley <jstanle2@uwo.ca>
Date: Tue, 01 Dec 2009 14:19:57 -0500
To: Gail Ryder <Gail.Ryder@LawsonResearch.Com>
CC: mbgupta@uwo.ca

Great Gail

Just send the form in the internal mail. In future, please make sure that Section 13.2 is completed to avoid any confusion.

Thanks,
Jennifer

Gail Ryder wrote:

Jennifer,

The room she is using for level 2 work is room A5-116 in the VRL which is a level 2 certified tissue culture room that contains a certified biological safety cabinet. She also has a fume hood in the general open lab area where the bench work is done.

I hope this clarifies things.

Also, I ensure that rooms are certified to level 2 containment if researchers are conducting level 2 work and I will not put my signature on the Biohazardous Agents Registry Form unless the room has been officially certified by myself. You can see on her BHARF for example that I added the room number on the first page along with my initials and room A5-116 was certified by me on August 7, 2008 (PHAC) and August 15, 2008 (CFIA).

Gail

Gail Ryder, CRSP
Research Safety Officer

Lawson Health Research Institute
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