The University *of* Western Ontario
BIOLOGICAL AGENTS REGISTRY FORM
Approved Biohazards Subcommittee: October 14, 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. Graham King**
DEPARTMENT:	**Hand and Upper Limb Centre, Bioengineering**
ADDRESS:	**Room B2-226, 268 Grosvenor St., London, ON**
PHONE NUMBER:	**519-646-6000 x. 65279**
EMERGENCY PHONE NUMBER(S):	**Louis Ferreira 619-4346, Jim Johnson 474-3195**
EMAIL:	**gking@uwo.ca**

Location of experimental work to be carried out :

Building :	**Lawson Health Research Institute**	Room(s):	**FB-102**
Building :	**St Joseph's Health Care London**	Room(s):	**B2-226**
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, CIHR, LHRI**

GRANT TITLE(S): **NSERC-Design and Biomechanical Analyses of Radial Head Elbow Implants, Computer Assisted Medical Interventions (CAMI), CIHR-Computer Assisted Surgery of the Elbow, Hemiarthroplasty of the Elbow, LHRI-Virtual Models for Motion Simulation**

UNDERGRADUATE COURSE NAME(IF APPLICABLE):

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

Name	UWO E-mail Address	Date of Biosafety Training
Josh Giles	**jgiles3@uwo.ca**	**2009/07/15**
Emily Lalone	**elalone@uwo.ca**	**2009/06/18**
Hannah Shannon	**hshanno4@uwo.ca**	**2009/06/18**

Jennifer Ng	jng54@uwo.ca	2009/06/18
Dan Langohr	glangohr@uwo.ca	to be taken Nov 15
Ryan Willing	rwilling@uwo.ca	2011/02/10

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.

Our research focuses on the evaluation of upper linmb biomechanics using fresh frozen cadaver specimens in our joint testing systems. As documented, these specimens have all been cleared via serological analysis. with respect to specimen testing, all dissections and preparations are conducted/supervised by orthopaedic or plastic surgeons from the HULC group. All lab personnel wear gloves, scrubs/labcoats and masks, and disposal of material is conducted commensurate with standard laboratory practice.

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

Our laboratory has developed a simulator that allows in-vitro testing of the elbow, forearm and wrist using load and motion control. This device has attracted interest from other researchers and from industry. Studies conducted using this device have provided important laboratory-based rationale for the treatment of patients afflicted with upper limb disorders.

Complete disruption of the elbow ligaments occur in patients with elbow dislocations. Stiffness and instability are common sequelae. We have applied our elbow testing system to evaluate and improve commonly employed treatments for ligament injuries of the elbow. Improved techniques for elbow ligament reconstruction have been developed and tested in our laboratory and have now been applied clinically. New approaches to the rehabilitation of patients with ligament injuries of the elbow have resulted as a consequence of our studies demonstrating the importance of forearm position and muscle activation on the stability of the ligament deficient elbow. We have recently evaluated the optimal method for collateral ligament repairs and reconstuctions of the elbow which have been widely adopted in clinical practice. We have also demonstrated the importance of the radial head as a stabilizer of the elbow, and compared different designs of prosthetic radial heads. These studies have influenced clinical practice. We have developed, patented and marketed a radial head replacement based on laboratory data. This implant is currently the most commonly used radial head prosthesis in the world and has had a major impact on the management of patients with radial head fractures, the commonest fracture of the elbow. More recently we have evaluated the role of the coronoid in stabilizing the elbow and developed clinical guidelines for surgical treatment based on these studies.

Our laboratory has conducted various studies on the use of tracking systems to quantify bone and joint motion. We have published extensively on the use of systems for biomechanical investigations to quantify the kinematics and stability of joints. Furthermore, the preparation of different algorithms to analyze this data has been conducted. We have developed expertise on the use of these approaches, particularly for kinematic studies of the elbow, wrist, shoulder and knee.

A recent thrust of our research program has been the design and development of measurement systems to be used intra-operatively, aimed at improving the outcome of joint alignment and implant reconstruction procedures. We have developed an instrumented load cell that measures independently the loads on the medial and lateral compartments of the knee, to assist in ligament resection and balancing procedures during knee arthroplasty. Using tracking technology, we have developed techniques to assist in the reconstruction of the hip, shoulder, wrist, and radial head of the elbow, with special interest in joint positioning and alignment. These systems have been laboratory-based to date, however forthcoming efforts are directed towards intra-operative use.

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:

Please attach the CFIA permit.

Please describe any CFIA permit conditions:

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
	☐ 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
	☐ 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

****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		☐ Yes ☐ Unknown		☐1 ☐2 ☐2+ ☐3
Human Blood (fraction) or other Body Fluid		☐ Yes ☐ Unknown		☐1 ☐2 ☐2+ ☐3
Human Organs or Tissues (unpreserved)	**Life Legacy, Tucson Arizona**	☐ Yes ☐ Unknown		☒1 ☐2 ☐2+ ☐3
Human Organs or Tissues (preserved)		Not Applicable		Not Applicable

Additional Comments: **specimens are serology tested and are known to be free of any infectious agents. Test s were for HIV 1/2 Ab, HBsAg, HCV Ab.**

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 7.0

6.2 If YES, please specify which biological agent will be used:
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?

6.5 Please give the Health Care Facility where the clinical trial will be conducted:

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 8.0

7.2 Name of animal species to be used

7.3 AUS protocol #

7.4 List the location(s) for the animal experimentation and housing.

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

7.6 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 9.0

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 10.0

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 11.0

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 12.0

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 **USA** ☐ NO
If **NO**, please proceed to Section 13.0

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 Graham King ***Date:*** October 11/2012

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): **BIO-LHRI-0087**

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:

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:
The area will be cleaned thoroughly (eye-wash station or washed). If a needle stick occurs, a visit to occupational health will be necessary.

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/workplacehealth.html

An X in the check box indicates you agree with the above statement... ☒
Enter Your Name Graham King ***Date:*** October 11/2012

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: October 22, 2012

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

Special Conditions of Approval:

------- Original Message --------
Subject: Re: Fwd: King B.A.R. Form - HULC Bioengineering Lab
Date: Thu, 18 Oct 2012 12:13:57 -0400
From: Jeff Tucker <Jeff.Tucker@sjhc.london.on.ca>
To: Hannah Shannon <hshanno4@gmail.com>
CC: Jennifer Stanley <jstanle2@uwo.ca>

Hi Hannah:

I have reviewed the documents sent (see attached) along with guidance from CFIA/PHAC on shipment requirement (also attached). These documents and the risk assessment provided by the supplier appear to confirm the BSL 1 designation. I would recommend these documents become part of the renewal application.

As such a laboratory inspection and certification by OHSS is not required under our program. Once you have completed the form as per Jennifer's comments on her email, please send it to me for my signature.

Regards,

Jeff

MACH 1 GLOBAL SERVICES, INC.

1530 W. Broadway Rd.
Tempe, AZ 85281
Tel: (480) 921-3900
Fax: (480) 921-3911

WAYBILL NUMBER

S00440932

House Bill # S00440932

PICK-UP DATE 09/24/12

DELIVERY DATE 09/26/12

FROM (Pick-up Location)	ACCT#	APC	AREA	TO (Delivery Location)	ACCT#	APC	AREA
	030301011	TUS	G			YYZ	

LIFELEGACY FOUNDATION
6825 EAST OUTLOOK DRIVE
TUCSON AZ 85756
UNITED STATES

PHONE # 520-575-5200

ST JOSEPH'S HEALTH CENTER
ATTN LOUIS FERREIRA/HANNAH SHANNON
268 GROSVENOR ST
LONDON ON N6A 4V2
CANADA

CONTACT

PHONE # 519-646-6000 XT61351

BILL TO	ACCT #
	030301011

LIFELEGACY FOUNDATION
6825 EAST OUTLOOK DRIVE
TUCSON AZ 85756
UNITED STATES

PREPAID	COLLECT	INCOTERM	
	X	FOB	

BILL OF LADING #

PURCHASE ORDER # 12-5097

CUSTOMER REFERENCE #

SERVICE LEVEL	NEXT DAY AIR	REQUESTED DELIVERY DATE	TIME
		09/26/12	17:00

CHECK BOX IF SHIPMENT CONTAINS DANGEROUS GOODS ☐

DECLARED VALUE $ 0.00 (AMOUNT)

SHIPPERS C.O.D. $ 0.00 (AMOUNT)

PIECES	DESCRIPTION	WEIGHT	DIMENSIONS
1	EXEMPT HUMAN SPECIMENS - DRY ICE	120.00	49x21x21

1	120.00

SPECIAL INSTRUCTIONS

I certify that this cargo does not contain any unauthorized explosives, incendaries, or hazardous materials. I consent to a search of this cargo. I am aware that this endorsement and original signature, along with other shipping documents, will be retained on file for thirty days. *

Shipper / Representative Date 9-25-12

Signature: x Rhett Spryer

Print Name: x Rhett Spryer

THANK YOU FOR USING Mach 1

RECEIVED BY Mach 1 DRIVER / AGENT

Driver Signature: _____

Print Name: _____

Date: _____ Time: _____

No. of Shipments This Stop: _____

Shipper must sign this bill and produce the proper identification. **One type of photo ID is acceptable if issued by employer or government.** If this cannot be furnished, the TSA requires 2 forms of ID, one of which must be government issued, non-photo.

Non Negotiable Airbill

1st personal ID reviewed:

appearing on ID

Matched photo on ID? YES ☐ NO ☐

2nd personal ID reviewed:

appearing on ID

Matched photo on ID? YES ☐ NO ☐

PROOF OF DELIVERY

Consignee SIGNATURE REQUIRED

X _____

CONSIGNEE NAME

PIECES

DELIVERING DRIVER'S NAME

DATE

TIME

It is agreed that the goods described herein are accepted in apparent good order and condition (except as noted) for carriage SUBJECT TO CONDITIONS OF CONTRACT ON THE REVERSE SIDE HEREOF. ALL GOODS MAY BE CARRIED BY ANY OTHER MEANS INCLUDING ROAD OR ANY OTHER CARRIER UNLESS SPECIFIC CONTRARY INSTRUCTIONS ARE GIVEN HEREON BY THE SHIPPER, AND THE SHIPPER AGREES THAT THE SHIPMENT MAY BE CARRIED VIA INTERMEDIATE STOPPING PLACES WHICH THE CARRIER DEEMS APPROPRIATE. THE SHIPPERS ATTENTION IS DRAWN TO THE NOTICE CONCERNING CARRIER'S LIMITATIONS OF LIABILITY.
Shipper may increase such limitation of liability by declaring a higher value for carriage and paying supplemental charge if required.
* The Terms and Conditions as noted on the reverse side of this Transport Document are not applicable for OCEAN shipments. These shipments will be subject to the Terms and Conditions of the appointed carrier, including Limitation of Liability.

COMMERCIAL INVOICE

SHIPPER		
LifeLegacy Foundation, Inc. 6825 East Outlook Drive Tucson, AZ 85756	Invoice No: 10183	Page 1 of 1
	Invoice Date: 9/24/12	Ship Date: 9/24/12
		File Number:

CONSIGNEE	BILL TO
St. Joseph's Health Center Attn: Louis Ferreira / Hannah Shannon 519-646-6000 x61351 / 519-619-4346 268 Grosvenor St. London ON, N6A 4V2 Canada	The University of Western Ontario Accounts Payable Suite 6100, Support Services Building London, ON N6A 3K7 Canada

RELATED ☐	NOT RELATED ☑	SOLD ☐	NOT SOLD ☑

--- SHIPMENT INFORMATION ---

Customer PO No: 551875	Letter of Credit No:	Mode of Transportation: Air Cargo
PO Date: 4/21/2011	Currency:	Transportation Terms:
Ref No:	Payment Terms: Prepay	Number of Packages: 1
AWB/BL No:	Incoterms Desc: DAP	Gross Weight(Kg): 49.8

Item No	Description Product No., Harmonized No. Country of Origin, Serial No.	Quantity	UOM	Unit Price	Total Price
1	Forearm (mid-humerus to fingertip)	8.0		$1.00	$8.00
2	Shoulder to mid-humerus	4.0		$1.00	$4.00
					$12.00

I declare all information contained on this invoice to be true and correct.

SIGNATURE Shipping Supervisor TITLE 9-24-12 DATE

LIFELEGACY

Anatomical Donation: The Legacy of a Lifetime™

Customs Department
Canada

Re: Shipment of cadaveric tissues to be used for motion testing and device implantation. These specimens will be tested at St. Joseph's Health Center in Ontario, Canada.

To Whom It May Concern:

A shipment of eight (8) forearm and four (4) shoulder specimens sent on September 24th, 2012 will be used for motion testing and device implantation. These specimens will be tested at St. Joseph's Health Center in Ontario, Canada. The identification numbers are;

Forearm: **12-07022 L&R, 12-09013 L&R, 12-09017 L&R, 12-09020 L&R**

Shoulder: **12-04024 L&R, 12-06040 L&R**

The specimens originated from Tucson, Arizona USA and are from legally consented for research tissue donors. They will be arriving in Ontario via Mach1 Global Services Inc. 480-921-3900 and will be frozen and packed in dry ice. The tissues have been serologically tested for (HIV ½ Ab, HBsAg, HCV Ab) and are negative and non-infectious. Please see the enclosed donor information sheets. The specimens are to be delivered to:

St. Joseph's Health Center
Attn: Louis Ferreira / Hannah Shannon
519-646-6000 x61351 / 519-619-4346
268 Grosvenor St.
London ON, N6A 4V2 Canada

Since it is essential that the tissue be kept frozen, we appreciate your help in expediting this delivery.

Sincerely,

George Calamayan, CTBS
Account Manager
LifeLegacy Foundation
6825 East Outlook Drive
Tucson, AZ 85706
520-575-5200

LIFELEGACY

6825 E. Outlook Dr.
Tucson, AZ 85756

500440932
12 pcs

Chain of Custody

DATE:	INVOICE:
9/24/2012	10183

If you are handling disposal of specimens, keep this document and Proof of Tissue Disposal form for your records.

BILL TO:	SHIP TO:
The University of Western Ontario Accounts Payable Suite 6100, Support Services Building London. ON N6A 3K7	St. Joseph's Health Center Attn: Louis Ferreira / Hannah Shannon 519-646-6000 x61351 / 519-619-4346 268 Grosvenor St. London ON, N6A 4V2 Canada

P.O. #:	TERMS:	Ship Date:	VIA:	BTM/Estimate#
577520	Net 30	9/24/2012	MACH 1	12-5097 / 3512

Quantity	DESCRIPTION	Date & Initials only LifeLegacy Use: Packaged	QC'd
1	Mid Humerus to Fingertip, Donor# 12-07022 Left	9/24/12 EM	9/24/12 DN
1	Mid Humerus to Fingertip, Donor# 12-09013 Left		
1	Mid Humerus to Fingertip, Donor# 12-09017 Left		
1	Mid Humerus to Fingertip, Donor# 12-09020 Left		
1	Mid Humerus to Fingertip, Donor# 12-07022 Right		
1	Mid Humerus to Fingertip, Donor# 12-09013 Right		
1	Mid Humerus to Fingertip, Donor# 12-09017 Right		
1	Mid Humerus to Fingertip, Donor# 12-09020 Right		
1	Shoulder(Clavicle,scapula-mid humerus), Donor# 12-04024 Left		
1	Shoulder(Clavicle,scapula-mid humerus), Donor# 12-06040 Left		
1	Shoulder(Clavicle,scapula-mid humerus), Donor# 12-04024 Right		
1	Shoulder(Clavicle,scapula-mid humerus), Donor# 12-06040 Right		
6	Serology Testing (CLIA Certified Laboratories only): HIV I/II, Hep B, & Hep C		
1	Dry Ice (First 25lbs)		
1	IATA Compliant Extra Large Packaging*		
1	Shipping & Handling Charges, Mach1#QPHX-5786		
1	Wire transfer fee		
1	MD Pathologist & Anatomist Case Investigation and Review Prior to Tissue Release		
1	AATB Accredited Tissue		
1	* Box with insulation, specimen wrapped in absorbent materials, double bagged and closed wit impermeable heavy duty plastic or heat sealed plastic bag.		
	1 - 175 = 110 lbs (25lbs Dry Ice)		
	Ice = 2 25kgs @ 5.65 Kgs LBS		
	5		
	2 - 2 KGS Dry Ice		

If specimens are returned to LifeLegacy for disposal, please include this document and all original labeling with returned tissue.

Tissue received by (Client)_____ **Date**_____ **Time**_____

Tissue returned to LLF by (Client)_____ **Date**_____ **Time**_____

Returned tissue received by LLF_____ Date_____ Time_____

DONOR INFORMATION LOG EXTERNAL VERSION

LIFELEGACY

DONOR INFORMATION

Donor Number	12-06040	Age	65
Sex	Male	Race	Caucasian
Primary COD			
Cardiac Death Date	6/21/2012	Time	13:35

RECOVERY AND PROCESSING INFORMATION

Recovery Date	6/23/2012	Time	02:30

PHYSICAL EXAMINATION INFORMATION

Actual Height in Inches	75.00	Actual Weight in Pounds	154.00
Actual BMI	19		

Physical Exam Findings:

M1-ID BAND R ankle
S1-5" scar medial L ankle
S2-6" scar lateral L ankle
S3-3" scar L hip
S4-3.5" scar R hip
S5-2.5" scar R hip
S6-5" scar lower L abd quad
S7-2.5"' scar midline upper abd
S8-4" scar anterior neck

SUMMARY OF MEDICAL HISTORY

Neuro Disorders:

Laryngeal CA with mets to Brain (05/2010), Depression (06/2010), and Siezures (06/2012).

Bone Disorders:

(L) Fx (1980) and Arthritis (2002).

Lung Disorders:

Laryngeal CA with mets to Lungs (05/2010)

Surgical Procedure:

Cervical Spine/Lumbar Sx (1993), Neck Sx/ Partial Laryngectomy/ Trach (05/2010) and Feeding tube 06/2010).

Other History:

Laryngeal CA w/ Mets to Brain and Lungs. ; Radiation - 08/2011; Chemotherapy - 09/2010
Smoked Cigarettes for 40 years. 2 PPD.
Socially drank whiskey.
No Additional History/Comments at this time...AMS...01/25/2012.
Medical/Social history updated...RDL...06/21/2012.

MEDICATION INFORMATION

Pain Medication.

SEROLOGY RESULTS

Serology Drawn		HBsAg	
Source		HCV	
Date Drawn	6/23/2012	HIV12	
Time Drawn	02:40	HTLV	
Person Recording Result	George Calamayan	RPR	
Received Date	6/27/2012	CMV	
Time	10:50	Other	

PROGRESS NOTES

Protocol for Infectious Substances and Other Biological Substances by Air and Road Transport

1) Introduction

Shipments should be packaged and labelled in accordance with regulations based on the method of transport. For AIR transport, the International Air Transport Association (IATA) Dangerous Goods (DG) regulations should be followed, and the Canadian Transportation of Dangerous Goods Act and Regulations (TDGR) from Transport Canada (TC) is used for ROAD transport.

2) Definitions

i. Human Pathogen

a. An infectious substance,
b. The toxin of an infectious substance, or
c. Any diagnostic specimen or other material that contains, or that its importer has reasonable grounds to believe contains, an infectious substance or the toxin of an infectious substance

ii. Infectious Substance

a. A microorganism or parasite that is capable of causing human disease, or
b. An artificially produced hybrid or mutant microorganism that contains genetic components of any microorganism capable of causing disease

iii. Animal Pathogen

a. Causative agent of reportable diseases,
b. Causative agent of any other disease that may affect an animal or that may be transmitted by an animal to a person,
c. Includes any animal pathogen derived through biotechnology,
d. Animal, animal product, animal by-product or other organism carrying an animal pathogen or part of one, or
e. Any other thing contaminated by an animal disease

3) Permit Requirements

Microorganisms are categorized into 4 risk groups. Microorganisms that are unlikely to cause disease in healthy humans or animals belong to risk group 1. Pathogens belonging to risk groups 2, 3 and 4 are infectious and pathogenic for humans and or animals (RG 4 posing the highest risk). Due to the risks associated with the manipulation of these items, import permits must be acquired from the Public Health Agency of Canada - Pathogen Regulation Directorate (PHAC-PRD) for infectious substances affecting humans (UN2814), and or for Biological Substances (UN3373). For infectious affecting animals (UN2900) a permit must be obtained from the Canadian Food Inspection Agency – Office of Biohazard Containment and Safety (CFIA-OBCS). It is possible that some items may require permits from both agencies.

4) Class 6.2

Substances that fall under class 6.2 are classified as infectious or non-infectious by the professional judgement of shipper based on factors such as known medical history, symptoms, individual circumstances or endemic local conditions. Specimens can fall into three categories:

i. Infectious Substances, Category A

These packages require a permit from PHAC-PRD and or CFIA-OBCS for import and must be clearly labelled as "Infectious substance, affecting humans/animals"

- Risk group 4
- UN2814 or UN2900
- Regulated packaging
- AIR: Packing Instructions 602
- ROAD: TC-125-1A

Further Information on packaging Protocol for Category A Shipments (AIR and ROAD):

Infectious substances fall into two categories: "*UN2814, Infectious substances, affecting humans*" and "*UN2900, Infectious substances, affecting animals*". If an infectious substance affects both humans and animals, they should be classified as "affecting humans". These substances should be clearly labelled and packed in accordance with IATA packaging instructions 602. Regulated TC-125-1A packaging is certified by Transport Canada and must include:

- Leak-proof primary container
- Leak-proof secondary container (ex: polypropylene vessel)
- Sufficient absorbent material placed between the primary and the secondary container to absorb the entire content of primary container if it is a liquid
- Multiple fragile primary receptacles must be individually wrapped or separated to prevent contact
- Cardboard coil
- Rigid outer packaging

Documents:

- Waybill (for Road or Air)
- Shipper's Declaration For Dangerous Goods (for air only)
- Importation permits (PHAC-PRD and or CFIA-OBCS)

ii. Biological Substances, Category B

These packages most likely require a permit from PHAC-PRD and or CFIA-OBCS for import. This includes shipment containing monkey and or non-human primate materials. It also includes diagnostic samples (human or animal) for testing for the presence of pathogens. In case of uncertainty, it is recommended to contact PHAC-PRD and or CFIA-OBCS directly to obtain further information).

- Risk group 2 or 3
- UN3373
- Non-regulated packaging
- AIR: Packing Instructions 650
- ROAD: TC-125-1B

Documents:

- Waybill (for road or air)
- Importation permits (PHAC-PRD and or CFIA-OBCS)

iii. Exempt Human/Animal Specimen

Usually consists of specimens being transported for routine screening tests or initial diagnosis (with the exception of testing for the presence of pathogens). A patient specimen is defined as human or animal materials collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention. A permit is most likely not required for this material and it is reasonable to assume that the material is non-infectious. However, a notice may be obtained from PHAC-PRD and or CFIA-OBCS to indicate that the material is reasonably believed not to contain any human or animal pathogens to facilitate the import (this is a courtesy letter, it is not a requirement).

- Risk group 1 or any non-infectious biological material
- No UN number
- Non-regulated packaging
- AIR: Packing Instructions 650
- ROAD: TC-125-1B

Documents:

- Waybill (for Road or Air)

NOTE (For Any Category): If you feel that a material within a package is suspicious or potentially infectious, first and foremost, **DO NOT open the package**. Please do not hesitate to contact PHAC-PRD and or CFIA-OBCS to obtain further information.

5) Other Biological Materials

According to IATA identification requirements (section 4) "Biological products manufactured and packaged in accordance with the requirements of national governmental health authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals" are not restricted or regulated. This category may include reagents with descriptions that include names of infectious substances. However, please note that the company responsible for the manufacture and shipping of these products is also responsible for proper labelling and packing of the items; if they have reasonable grounds to believe that the product is infectious, they are responsible for labelling as such (consistent with the labelling and packing requirements for infectious substances affecting humans/animals, UN 2814/ UN2900).

6) Points to Remember

- Imported materials that require a permit from the PHAC-PRD and or CFIA-OBCS, should be clearly labelled as "Infectious substance, affecting humans/animals" or "Biological Substances, Category B" and be packaged in accordance with packing instruction 602 or 650 respectively.
- If the infectious material can also cause disease in animals, this will be clearly stated on the PHAC permit as "*Pathogen(s) indicated on this permit also require an accompanying valid CFIA-OBCS permit for importation". Please ensure that a CFIA-OBCS permit does accompany the shipment.
- CFIA-OBCS permits to import animal pathogens will also indicate whether a PHAC permit is required, on the 3rd page of the permit.
- PHAC-PRD and CFIA-OBCS permits come in two forms, a multiple entry permit (permitting multiple imports over the span of one year) and a single entry permit (permitting one entry in a 3-month span), please verify these dates with the shipment.
- For all shipments of biological products labelled as non-infectious or free of pathogens, ensure that the shipper/exporter and consignee is a bona fide laboratory, clinic, hospital, testing facility, etc. and not an individual.
- Again, if you feel that a material within a package is suspicious or potentially infectious, first and foremost, **DO NOT open the package**. Please do not hesitate to contact PHAC-PRD and or CFIA-OBCS to obtain further information.

7) Contact Information

Pathogen Regulation Directorate
Public Health Agency of Canada
100 Colonnade Road, AL: 6201A
Ottawa, ON, K1A 0K9

Tel: 613-957-1779
Fax: 613-941-0596

permit_permis@phac-aspc.gc.ca
http://www.phac-aspc.gc.ca/ols-bsl/index.html

Office of Biohazard Containment & Safety
Canadian Food Inspection Agency
1400 Merivale Road
Ottawa, ON, K1A 0Y9

Tel: 613-773-6520
Fax: 613-773-6521

ImportZoopath@inspection.gc.ca
http://www.inspection.gc.ca/english/sci/bio/bioe.shtml