

**The University of Western Ontario**  
**BIOLOGICAL AGENTS REGISTRY FORM**  
 Approved Biohazards Subcommittee: October 14, 2011  
 Biosafety Website: [www.uwo.ca/humanresources/biosafety/](http://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, 1<sup>st</sup> 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](mailto: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](mailto: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/](http://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:	<b>Dr Aaron Fenster</b>
DEPARTMENT:	<b>Imaging Research Lab, Robarts Research Inst</b>
ADDRESS:	<b>100 Perth Drive, London, ON N6A 5K8</b>
PHONE NUMBER:	<b>519-931-5707, 25707</b>
EMERGENCY PHONE NUMBER(S):	<b>519 931-5708, 25708</b>
EMAIL:	<b><a href="mailto:afenster@imaging.robarts.ca">afenster@imaging.robarts.ca</a></b>

Location of experimental work to be carried out :

Building : <b>Robarts Research Inst</b>	Room(s): <b>3<sup>rd</sup> floor pathology</b>
Building : <b>CSTAR, University Hospital</b>	Room(s): <b>8th floor animal lab</b>
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: **OICR (Ontario Institute for Cancer Research), LRCP (London Regional Cancer Program)**

GRANT TITLE(S): **Imaging Translation Platform, LRCP Small grant**

UNDERGRADUATE COURSE NAME(IF APPLICABLE): **N/A**

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

Name	UWO E-mail Address	Date of Biosafety Training
<b>Cathie Crukley</b>	<b><a href="mailto:ccrukley@uwo.ca">ccrukley@uwo.ca</a></b>	<b>Feb 9, 2011</b>
<b>Hamid Sadeghi Neshat</b>	<b><a href="mailto:hsadegh3@uwo.ca">hsadegh3@uwo.ca</a></b>	<b>Feb 6, 2012</b>
<b>Derek Cool</b>	<b><a href="mailto:dcool@uwo.ca">dcool@uwo.ca</a></b>	<b>TBD</b>
_____	_____	_____
_____	_____	_____



**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:** Minimally-invasive cancer therapies are continually evolving and, when effective, are preferred to open surgical approaches due to lower complications rates and shorter recovery times. Percutaneous intervention, such as radio-frequency (RF) and microwave (MW) ablation of malignant tissue is a rapidly expanding research field and a treatment tool for those patients who are not surgical candidates or as a first-line cancer therapy. The RF and MW ablation probes are large needles that cause localized tissue heating and cell death through either RF or MW thermal induction. The clinical benefit of this technology is that accurate insertion of the probe into the organ can achieve good local eradication of the tumour without requiring the patient to undergo general anesthesia or an open surgical resection. However, unfortunately, both ablation methods often have a higher local recurrence rate than surgical resection, mostly due to insufficient or inaccurate local ablation of cancerous cells

**Purpose:** To improve our knowledge of and accuracy using ablation probes to ablate, or burn, malignant tumours in humans for minimally-invasive cancer therapy. 1) To measure the volume of liver and kidney tissue that is killed as angle of placement between 2 or more probes is varied. 2) To correlate the ablated tissue volume seen at the cellular level with the changes seen on ultrasound imaging during the ablation.

**Summary of the methods:** This is a medical research, acute pig study involving major surgery performed under gas anesthesia (as opposed to the local anesthesia in most human cases) to evaluate ablation technology used for cancer therapy. A clinical expert (an interventional radiologist or radiology resident) will insert the standard thermal ablation needles through the abdomen wall into the liver and kidney following the same clinical standard protocols as for humans. We will ablate multiple locations within the liver and kidneys without overlapping burns (in-vivo, at CSTAR). Angle between the needles and their location within the tissue (proximity to major vessels) will be the variable in our research. 3D ultrasound guidance system developed and tested in Robarts imaging laboratories will be used both to guide the insertion procedure and the final location of the needles within the tissue will be monitored in-vivo (in CSTAR) for increased accuracy and comparison purposes. Standard ultrasound machines will be used with a mechanical mover to reconstruct volumetric images of the needles/target. Following the procedure, the clinical team will harvest the ablated tissue and fix it in formalin following the standards. Fixed tissue will be then transferred to Robarts pathology lab in leak proof containers. Pathology experts will process and image the specimen using the standard pathology equipment to slice and acquire images of the ablated tissue after fixation. A high resolution camera will be used to acquire images of the sliced tissue. Graduate students in Robarts Research Engineering will then evaluate the ablated tissue volume in histology and correlate them with the ultrasound findings and needle positions.

**Expected Benefit:** We will quantify the extent of liver tissue destruction caused by varying the probe positions and orientations and use it to predict the ablation volume in humans, which is essential to ensure complete eradication of the tumour. Furthermore, understanding of how ultrasound image changes correlate with tissue destruction, will allow for better assessment of the ablation progression in patients. Finally, we hope to reduce the time required for the ablation procedures, the recurrence rate due to insufficient ablation and the capital cost associated with such procedures.

**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
N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 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](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	<input type="checkbox"/> Yes <input type="checkbox"/> No		Not applicable
Rodent	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Non-human primate	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Other (specify)	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Rodent	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Non-human primate	<input type="checkbox"/> Yes <input type="checkbox"/> No			
Other (specify)	<input type="checkbox"/> Yes <input type="checkbox"/> No			

\*Please attach a Material Safety Data Sheet or equivalent from the supplier. (For more information, see [www.atcc.org](http://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		<input type="checkbox"/> Yes <input type="checkbox"/> Unknown		<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
Human Blood (fraction) or other Body Fluid		<input type="checkbox"/> Yes <input type="checkbox"/> Unknown		<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 3
Human Organs or Tissues (unpreserved)		<input type="checkbox"/> Yes <input type="checkbox"/> Unknown		<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 2+ <input type="checkbox"/> 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](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 **Porcine liver and kidney**

7.3 AUS protocol # **submitted; pending approval**

7.4 List the location(s) for the animal experimentation and housing. **CSTAR, in vivo - Robarts fixed tissue process**

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<sub>50</sub> (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](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  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 Aaron Fenster Date: 012/01/30**

**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:

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:

**We will be working with the fixed tissue, in the case of injury with needle we will express the wound to bleed, wash the wound for 5 mins with water and soap and report to staff/faculty of health**

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 Aaron Fenster Date: 2012/01/30



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: Ronald Nicosky  
Date: Feb. 06, 2012

Approval Number: \_\_\_\_\_ Expiry Date (3 years from Approval): \_\_\_\_\_

Special Conditions of Approval: