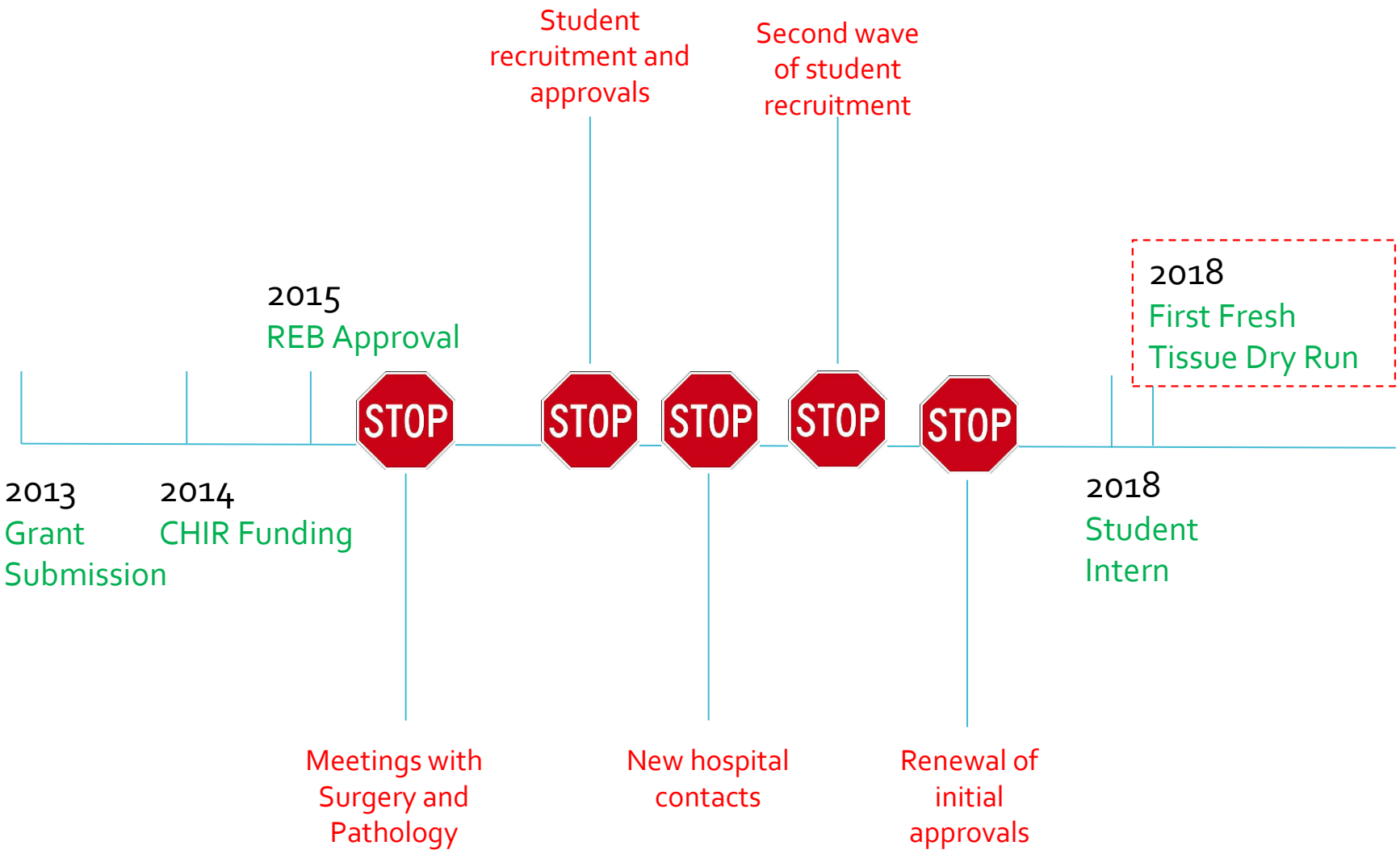
Fresh Tissue Trials August 31 Workshop

Jenna Jones

About Me

- University of Western Ontario
  - Medical Science and Psychology
- University of Windsor
  - MSc Biological Sciences
- University of Western Ontario
  - Diploma Clinical Trial Management
  - **Internship: University of Windsor – Dr. Lisa Porter**
    - **Fresh Tissue Trials**

Where we started



What Now?

- **We needed a "checklist"**
- 1. Contacts and meetings, the key people to consider
- 2. Development of protocols
- 3. Student approvals and training
- 4. Tools and documentation

* Always important to inform and involve Clinical Trials Department at all stages of fresh tissue trials

1. Meetings and Contacts

Develop meetings and contacts

Checklist for Fresh Tissue Trials

1. Establish the following contacts:

	Contact
Surgery Collaborators	
Pathology Collaborators	
Clinical Trial Main Contact	
Surgery Location	
Surgery Contact (Title)	
Who is Providing Informed Consent?	
Individual Contacting Lab when Tissue Available	
Lab Contacts	
Method of Pick up/Delivery	

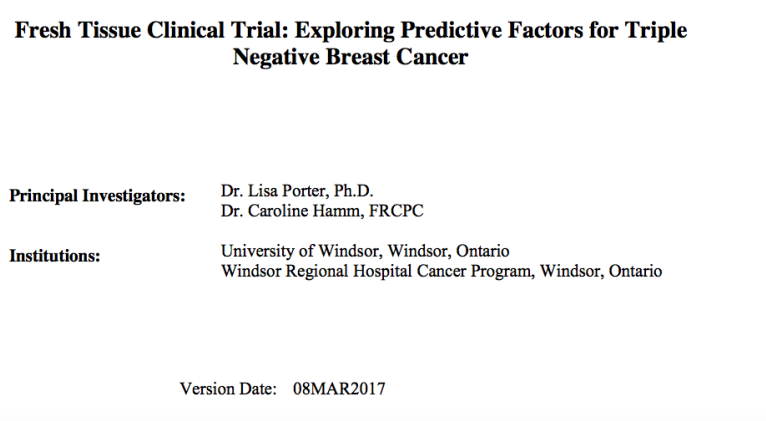
2. Set date for team meeting: _____
3. Develop protocols and consent forms (See fillable forms, linked below)
    a. Fresh tissue trial protocols
    b. Consent forms
4. Set a date for dry run of trial: _____

2. Protocols

Develop your protocols

Protocol and informed consent documentation will differ depending on fresh tissue trial

Developed templates to work with, highlighting areas where they will differ

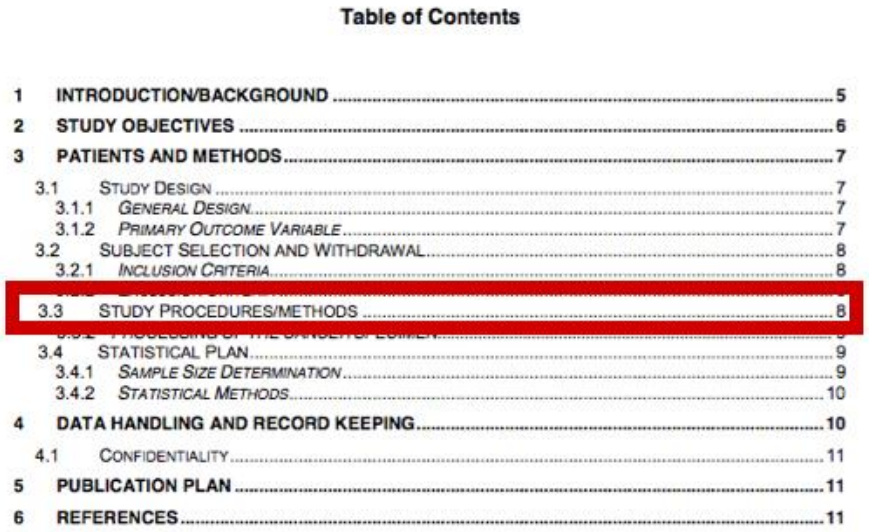


Fresh Tissue Clinical Trial: Exploring Predictive Factors for Triple Negative Breast Cancer

Principal Investigators: Dr. Lisa Porter, Ph.D.
Dr. Caroline Hamm, FRCPC

Institutions: University of Windsor, Windsor, Ontario
Windsor Regional Hospital Cancer Program, Windsor, Ontario

Version Date: 08MAR2017



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- All templates can be found on WCRG website

Develop your informed consent documents

CTO Clinical Trial Informed Consent Form Template

Instructions:

This Clinical Trial Informed Consent Form (ICF) Template has been designed to meet current regulatory and ethical standards.

The study-wide (provincial) ICF template uploaded into the Provincial Initial Application should follow the prescribed structure and format as set out in this template.

How to use this template:

- Suggested text/examples in blue font may be omitted if they are not relevant to the specific protocol
- All text included in the study-wide ICF must be applicable/appropriate for that specific clinical trial
- Instructions are indicated in *italics/grey background*
- Turquoise highlighting provides a prompt to adapt text to the research study (e.g., to select from the available options highlighted)
- Text with yellow highlighting reflects instructions for participating centres to follow when creating their local ICF. This text, including the highlighting, should not be altered or removed from the ICF that is uploaded into the Provincial Initial Application through CTO Stream
- When developing their local ICF, participating centres should follow the instructions and insert the applicable centre-specific content. The instructions and highlighting should be deleted from the local consent form submitted to the REB of Record

- All templates can be found on WCRG website

3. Student approvals and training for tissue transport

Required Documentation

- **University of Windsor Requirements:**
- Valid driver's licence
- Insurance Declaration from University of Windsor
  - Students will need to be an employee of the University of Windsor for insurance purposes
- WHMIS 2015 training
- BSL (Biosafety) training

Required Documentation

- **Windsor Regional Hospital Requirements:**
- "Student Declaration of Understanding" – Insurance purposes
- Two step TB skin testing
  - Typically takes between 2-3 weeks for full testing to be complete
  - Also requires up to date immunizations (approximately 1- 2 weeks to complete depending on student)
- Vulnerable Sector Check
  - Depending on which municipality student is from, can take between 1- 2 weeks
- Privacy and Confidentiality Agreement
- Ethics Certification (Ethical Conduct of Research Involving Humans)
- Review and Completion of the Clinical Student Handbook Review Questionnaire

4. Tools and Documentation

Tools Developed

- First Meeting Agendas
- Protocol and Informed Consent
- Student Approval and Training Guidelines
- Pathology Forms
- Ethical Guidelines
- Health and Safety Clearance/ Job Descriptions for Students
- Fresh Tissue Dry Run Protocols

- All templates can be found on WCRG website

Pathology Forms

WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

CLINICAL SPECIMEN RELEASE REQUEST

*** Note changes to tissue handling ***

CONTACT INFORMATION		
Requester (Please Print):		**Date:**
Phone:	**Pager:**	**Email:**
Principal Investigator:		

PURPOSE
Protocol #/ Study Name:

Special Handling Material Requested:

Fresh Tissue – 10% of tumour specimen if appropriate and will not jeopardize diagnostics

Anatomic Site:

Tissue Type:

Amount:

Special Handling: **DO NOT PLACE IN PARAFFIN/ FORMALIN**

Approved personnel for pick up:

Approved personnel for transport:

WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Please Present the Following:

- **Signed Patient Consent form for study**

For Pathology Department Use Only	
☐ **Approved**	☐ **Denied**
Comments: • **Amount of material is dependent on amount available, at the pathologists' discretion** • **Only resection material** • **Needle core biopsies excluded**	
Signature:	**Date:**

Ethical Guidelines

Suzanne McMurphy

Translational Research Ethics Processes

1. **Where can the REB forms be found?**
   All application forms can be obtained from the University of Windsor REB website including Windsor Regional Hospital (WRH) and Hotel-Dieu Grace Healthcare (HDGD): http://www.uwindsor.ca/research-ethics-board/
2. **If more than one REB is involved, which one do we submit to first?**
   The research team should submit first to the REB at the institution where the PI is primarily associated. For example, if the PI's primary affiliation is with the University of Windsor, then the research team should submit to the University of Windsor REB first. If the PI's primary affiliation is with WRH, then the team should submit first to WRH's REB first. If the PI is from another institution, then the research team should submit to the PI's institution first, then to the University of Windsor.
   The exception to this policy occurs when one REB may defer to another REB regarding site-specific recruitment or protocol procedures. For example, if the PI is affiliated with the University of Windsor, but the protocol is implemented at WRH and some procedures are in question, the University of Windsor REB may defer to WRH REB to conduct the initial review.
3. **When should I consult with University of Windsor Health and Safety?** If the research takes place within a lab at the University of Windsor, or the protocol involves gathering biological specimens, then the researchers should consult with the University of Windsor Health and Safety to ensure that their current Health and Safety certificate covers the specific protocol, or if an addendum is necessary. If the researcher does not have a current Health and Safety Certificate, then one needs to be obtained prior to receiving REB clearance.
4. **How is the level of REB review determined?**
   The level of REB review depends upon the risks to participants. Protocols containing Risks that are more than minimal will be reviewed at the Full Board level, risks that are no more than minimal risks (assessed per participant's experience in everyday life; for example, if the participants are cancer patients currently undergoing treatment, then their risks would be assessed differently than the general population as they would be exposed to different procedures in their everyday life than would the general population).
   Secondary use of data and protocols cleared by another institution can be reviewed at the Executive level by either the Chair only, or the Chair plus one additional Board member.
5. **How long does it take for my protocol to be reviewed?**
   Review at the executive level by UWindsor REB, depending on which level the fresh tissue trial falls under, the following will need to be considered:
   a. Chair level: review daily
   b. Delegated level: meet once/week
   c. Full board review: meet once/month

Ethical Guidelines

Suzanne McMurphy

Step 1: Completing REB forms

If Windsor Regional Hospital, staff or patients are involved in the research, use Windsor Regional Hospital REB Forms:
http://www.uwindsor.ca/research-ethics-board/304/windsor-regional-hospital

If Windsor Regional Hospital is not involved, use the University of Windsor REB Forms:
http://www.uwindsor.ca/research-ethics-board/298/forms

If Hotel- Dieu is involved, use the University of Windsor REB Forms:
http://www.uwindsor.ca/research-ethics-board/298/forms

Step 2a: Determine Principal Investigator Affiliation

If the PI is from Windsor Regional Hospital:

1. Complete Windsor Regional Hospital forms and submit to Windsor Regional Hospital REB
2. Once protocol is approved by Windsor Regional Hospital, completed forms sent to University of Windsor REB for clearance

If the PI is from the University of Windsor, but Windsor Regional Hospital is involved:

1. Complete Windsor Regional Hospital REB forms from Step 1, but submit to University of Windsor REB first
2. Once cleared by University of Windsor, completed forms sent to Windsor Regional Hospital

If the PI is from the University of Windsor and Windsor Regional Hospital is not involved:

1. Complete the University of Windsor REB forms and submit to University of Windsor REB

Step 2b: Ensure University of Windsor Health & Safety certificate is obtained or is cleared by University of Windsor Health and Safety that existing certificate covers the specific protocol prior to submission to University of Windsor REB

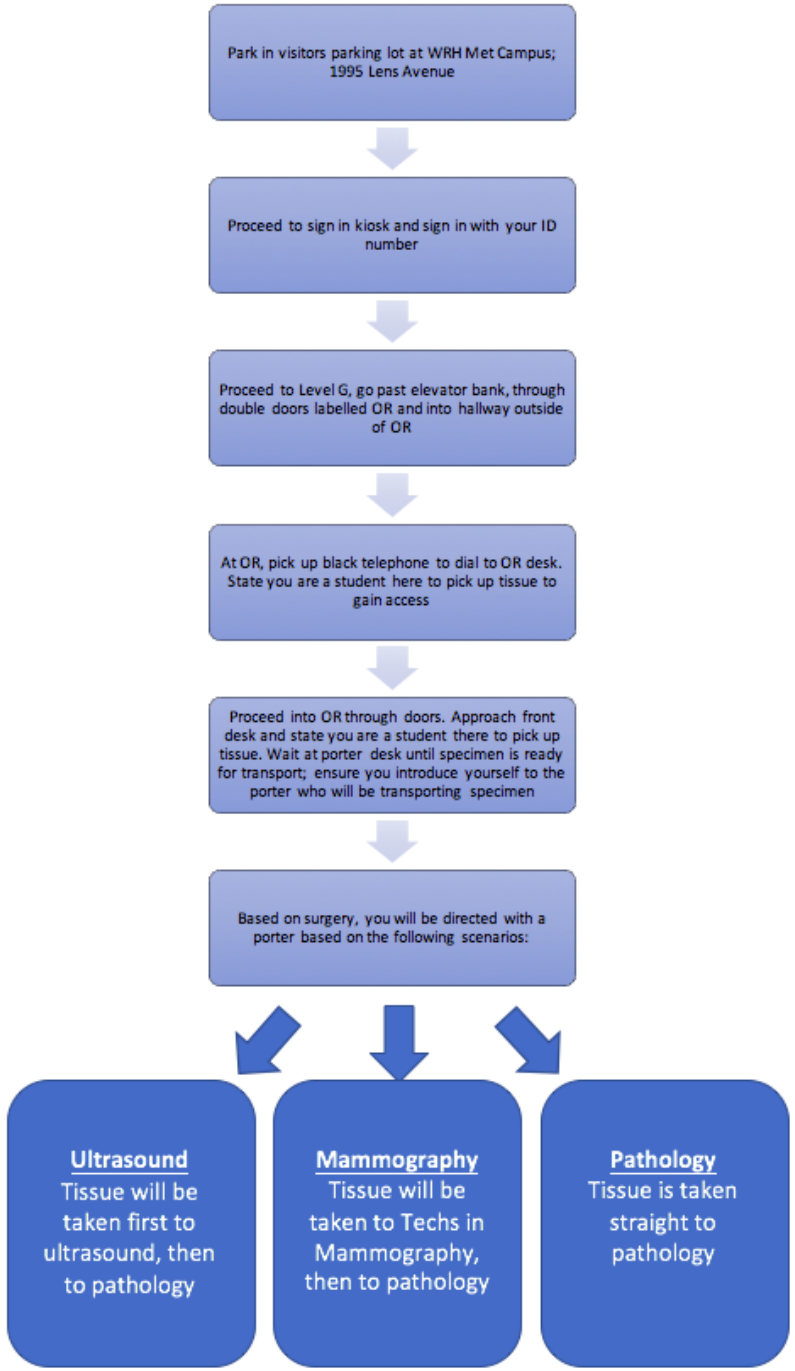
Health and Safety

Sherri Menard
Daniella Beaulieu

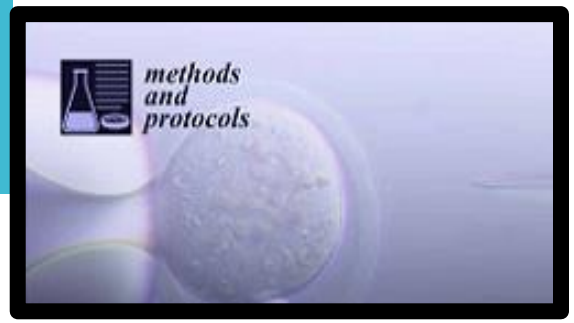
- Two options:
  - **Paid University of Windsor employee**
  - Insured with University – Insurance Declaration
  - Volunteer services at Windsor Regional
  - **Paid student volunteer**
  - *Work in progress*
  - Job descriptions including stipend information and insurance

First Fresh Tissue Dry Run!

Krista Naccarato

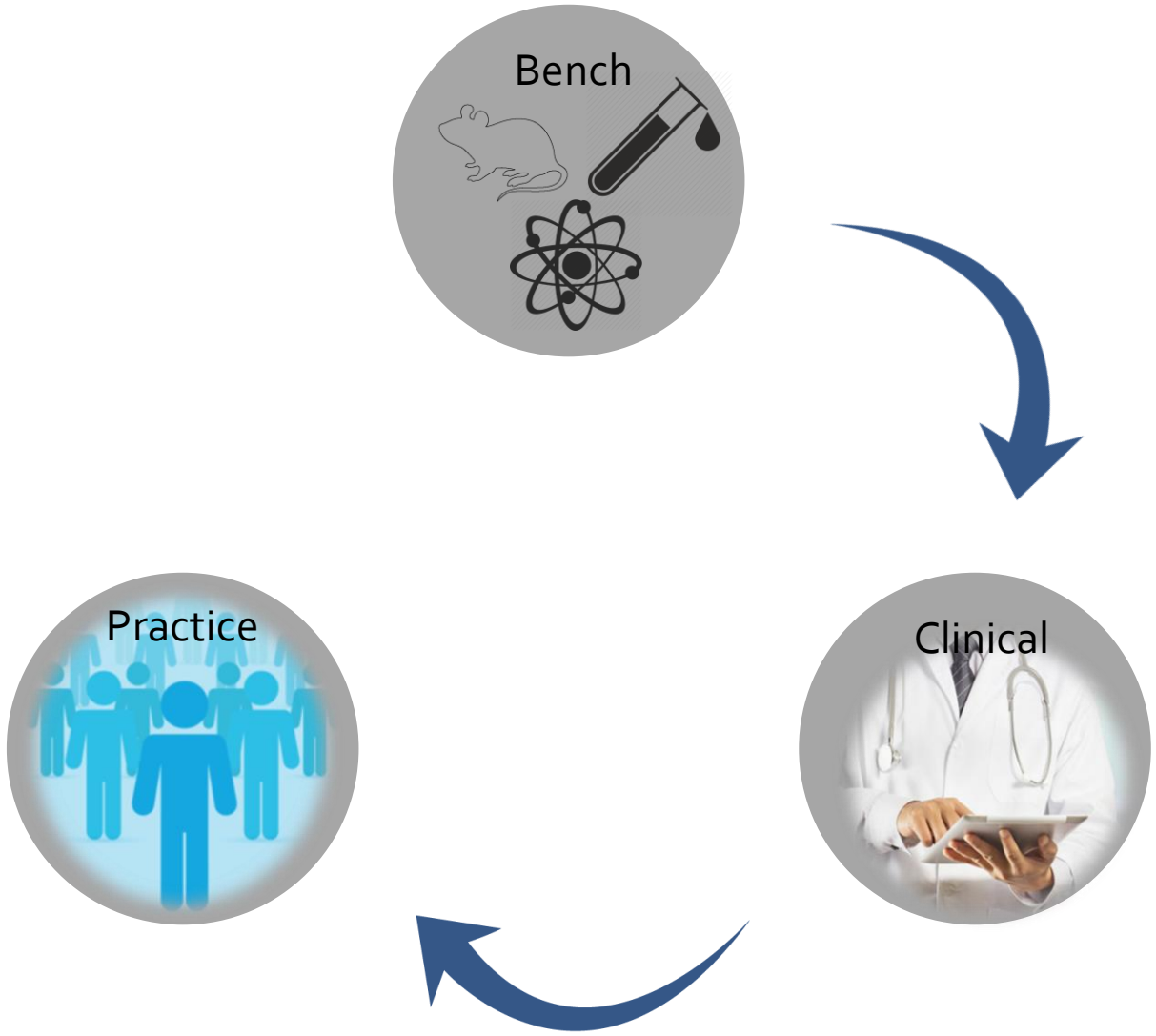


What have we achieved?

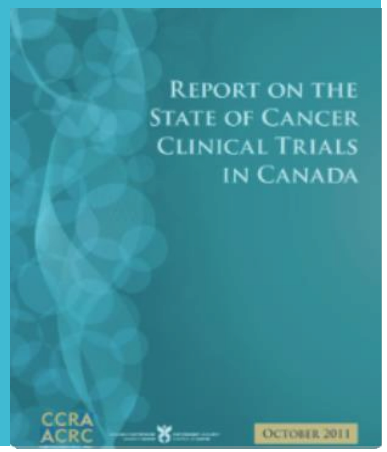


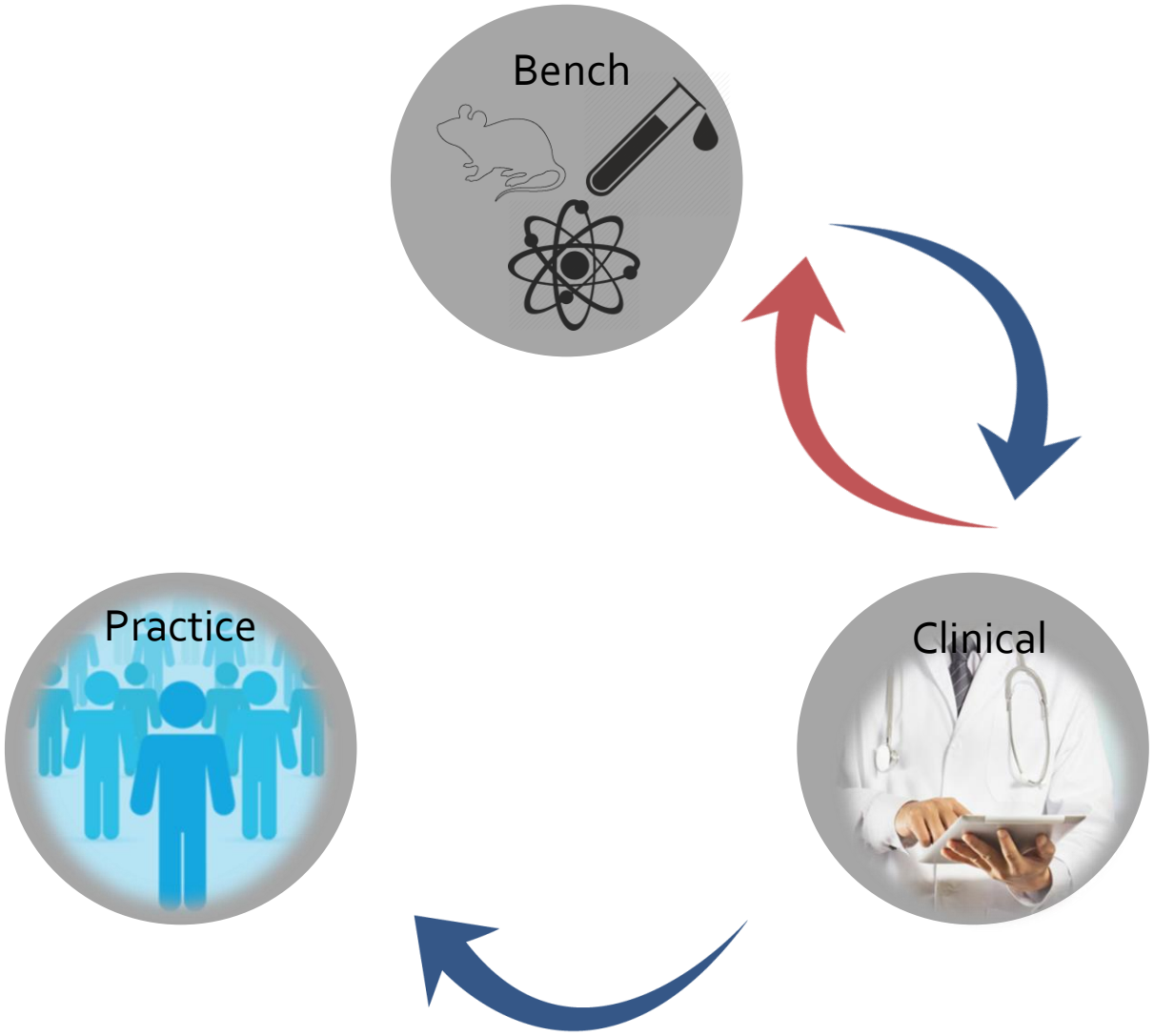
- 1. Fresh tissue trial walk through
- 2.Tools and documentation for future fresh tissue trials
  - Located on WCRG website
- 3. Publication submission

Innovative and cutting edge research



"…Improved outcomes for patients treated in institutions with an active clinical research program"





THANK YOU

- Suzanne McMurphy
- Karen Metcalfe
- Bre-Anne Fifield
- Sherri Menard
- Daniella Beaulieu
- Krista Naccarato
- Lisa Porter
- Caroline Hamm
- Connie Tomalty