The Terry Fox Research Institute
L'Institut de recherche Terry Fox

COEUR *Ovarian Cancer Pan-Canadian Program*
Programme pan-canadien en cancer de l'ovaire

Canadian Ovarian Experimental Unified Resource (COEUR)

Biological Material and Data Request Form

A Pan-Canadian platform for the development of biomarker-driven subtype specific management of ovarian carcinoma (COEUR program) was initiated in 2009 with the financial assistance of the Terry Fox Research Institute (TFRI).

COEUR was formed through a consortium of leading Canadian investigators in ovarian cancer biomarker research. The specific aims of the program are:
1) To develop a pan-Canadian discovery and validation platform for biomarker research
2) Use the biomarker platform to:

- *To develop a molecular-pathology classification system for ovarian cancer integrated into clinical nomograms (decision making algorithms) for rational clinical management.*
- *Validate biomarkers that can be used in the stratification of ovarian cancer patients that result in an improved clinical management.*

3) To articulate this correlative pre-clinical initiative with prospective clinical trials in order to expedite the translation of research findings to clinical practice.

The central research platform is based on a pooled retrospective collection of human biological material (including frozen tissues, blood DNA, ascites cells and fluids, FFPE samples, TMA) with associated clinical data. COEUR has been created to promote access, ensure quality, and provide standardization of material and data resources for biomarker validation in ovarian cancer. COEUR is meant to not only facilitate biomarker research, but to promote the translation of new finding into the clinical arena. The resources currently available in the COEUR are as follows:

- Frozen tissues
- Blood DNA
- Ascites fluids
- FFPE blocks
- TMA

Application process

The study committee will evaluate the research proposal and review preliminary data presented by applicants**. Please note that the COEUR resource is not to be used for discovery-based research, but is a platform for biomarker validation**. The study committee will evaluate the research proposal (please respect the word restriction allocated) and the probability of success based on the number and quality of samples/ cohorts/ control groups used in preliminary studies, comparisons of existing biomarkers with minimal acceptable improvement in performances, and quality and specificity of probes (antibodies, primers, etc…).

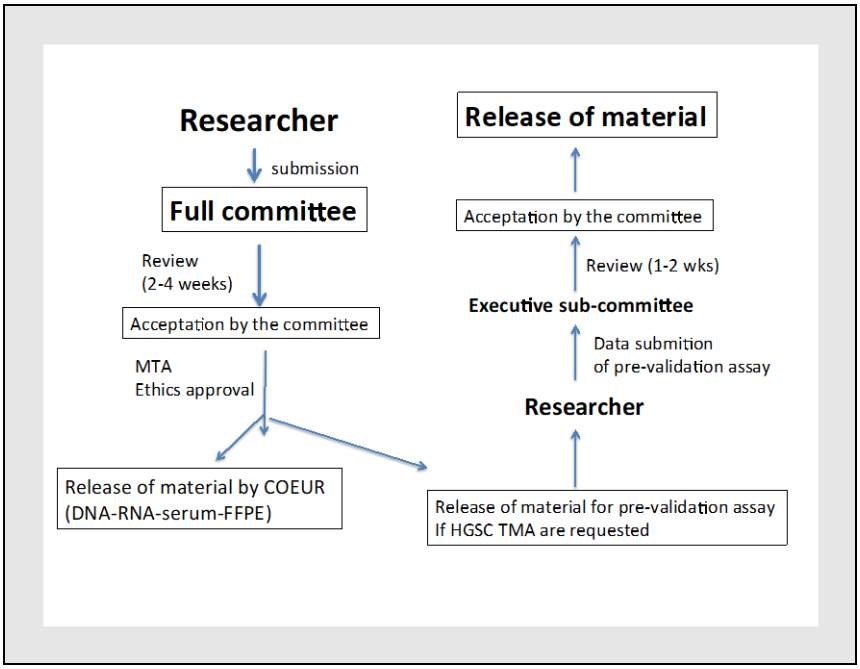
Applicants may wish to refer to the publication by R. Simon and D.G. Altman (Br J Cancer 1994), which describes several criteria that should be respected in validation studies.

We encourage you to provide in your application all pertinent information (references, manuscript, images) to help the Study Committee to estimate the performance of these criteria.

Note that access to the COEUR repository will always be conditional on the approval of the project by the Research Ethics Board at your institution. **Recipients of COEUR resources must be willing to sign a Material Transfer Agreement and to deposit results and data in the COEUR repository at the end of the study**.

Please note the 3 annual application deadline: March 31^{tst}, July 31st and November 30th. Application received the day after the deadline will be evaluated at the next Study Committee.

Application process Summary



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Biological Material and Data Request Form

TITLE

PI name:

Proposed start date of use:

Use: ☐ academic ☐ non-academic

1 Requested material

1.1 Clinical data and/or biomarker data only ☐

1.2 Type of requested tissue

Primary ☐ **Recurrence** ☐ **Ascites fluids** ☐ **Recurrence (Ascites fluids)** ▪ **Blood** ▪

Condition of tissue preservation	Condition of tissue preservation	Condition of tissue preservation	Condition of tissue preservation	Condition of tissue preservation
☐ Frozen ☐ Paraffin sections ☐ Tissue array ☐ Frozen tissue cut or section ☐ Blood DNA	☐ Frozen ☐ Paraffin sections ☐ Tissue array ☐ Frozen tissue cut or section: ☐ Blood DNA	☐ DNA ☐ Non-cellular fraction	☐ DNA ☐ Non-cellular fraction	☐ Plasma ☐ DNA ☐ Serum

2 Summary of requested material

2.1 List of requested material

	Tissue type See section	Biological material description histopathology	Grade	Stage	Number of cases per tissue type	Number of samples per case.	Requested quantity per sample
Examples	Ovary-primary	Tissue Array - Serous	2	4	8	All	20 *u*g
1							
2							
3							
4							

2.2 Selection criteria:

☐ Age range: Min Max ☐ Not applicable
☐ Family history required ☐yes ☐ no
☐ Chemotherapeutic treatment type:
☐ Other:__ex: RIN level of RNA, etc

- ➢
- ➢

2.3 Comments and additional explanations re: samples requested

3 Principal investigator's profile

3.1 Principal investigator (PI):

Title	Surname	First Name	
Institution/Company		Department/Division	
Address Civic number, street			
Room	Building name		
City	Province/State	Postal Code	Country
Telephone 1	Telephone 2	E-mail address	Fax

3.2 Resource person (contact):

☐ Principal investigator (same as mentioned above)

Title	Surname	First name	
Institution/Company		Department/Division	
Address Civic number, street			
Room	Building name		
City	Province/State	Postal code	Country
Telephone 1	Telephone 2	e-mail address	Fax

3.3 Shipping address

☐ Same as principal investigator ☐ same as resource person (contact)

Shipping contact	Room number	Building name	
Department and/or Institution		Department/Division	
Address Civic number, street			
Room			
City	Province/State	Postal code	Country
Telephone 1	Telephone 2	E-mail address	Fax

3.4 Co-Investigators(s):

Co-investigator			Affiliation	
Title	Surname	First name	Institution/Company	City

4 Summary of the study

4.1 Study title

4.2 Investigated disease (histopathological subtype, recurrence, etc…)

4.3 Summary (a maximum of 250 words summary of the planned study**)**

4.4 Hypothesis (a maximum of 100 words summary)

4.5 Relevance of the study to cancer and TFRI project (a maximum of 150 words**)**

4.6 Experimental approach (summarize your experimental approach and specificity of validation methods to be used, a maximum of 500 words)

4.7 Statistical analysis (summarize your statistical analysis plan and justify the number and the quantity of requested samples,) . Please provide for TMA analysis:

4.8 Proof of concept and feasibility of the study: (supporting preliminary data should be attached, i.e. images,).

Please provided:

- Positive and negative staining controls and all pertinent informations about antibody supporting the specificity of detection of your biomarkers (normal TMA tissue, comparison to a second antibody, western-blot showing knock out, correlation with other genomic variables such as mutation, ect….).
- For IF on TMA: absence of cross-hybridization with secondary antibodies.

4.9 Funding from another institution to support the study

☐Funds not available for this study at the present time ☐Study has been submitted for funding. Organization: ☐Study is funded or funds are available for this study from another source. Organization :

4.10 Budget if no funding available from another institution to support the study (for reagents and service, equipment can be including in the budget) (a maximum of one page)

4.11 Study duration (Be prepared to submit a short report on requested material used, at the end of the present study**)**

4.12 Scientific review

☐ Project has been approved by a peer review panel
Organizations and coordinates:
Award number:
Period covered by Term of Award:
☐ Project has been submitted to a peer review panel
Organization:

☐ Others

4.13 Ethical committee approval

☐ Approval received
☐ Project is under review
☐ Project is not yet submitted

4.14 Intellectual Property protection process

☐ Not patentable
☐ Not yet done
☐ In preparation
☐ Pending / provisional
☐ Accepted (patent number:)

4.15 The following appendices are required by the investigators, when available.

☐ Ethical committee approval Project name
☐ Principal investigator's short CV
☐ Project award letter Project name
☐ Preliminary data and/or biomarker validation data

If appropriate, the following appendices should also be attached

☐ Co-Investigator's CV: Name of the file(s)

☐ Detailed description of the study, if project not approved by a peer review panel

5.0 Security and confidentiality

Proposed measures for the physical safety of the tissues: (ex: Will the freezer be locked? Who will have accesses to it?)	
Proposed electronic measures for clinical data safety: (ex: Are computers protected by passwords? Who accesses them	
Will tissue and/or data treatment and analysis be carried out by outsourced personnel? If yes, please explain (ex: genomic platform)	

A Material Transfer Agreement (MTA) is presently being developed for the TFRI-COEUR project. I understand that my application may be financed, and I will receive samples, only after this MTA has been approved and signed by all concerned parties.

I also understand that the MTA defines the requirement for me to deposit the results and data generated from my experiments with the COEUR resources into the COEUR repository, and I agree to these conditions.

Signature: _____ Date: _____