

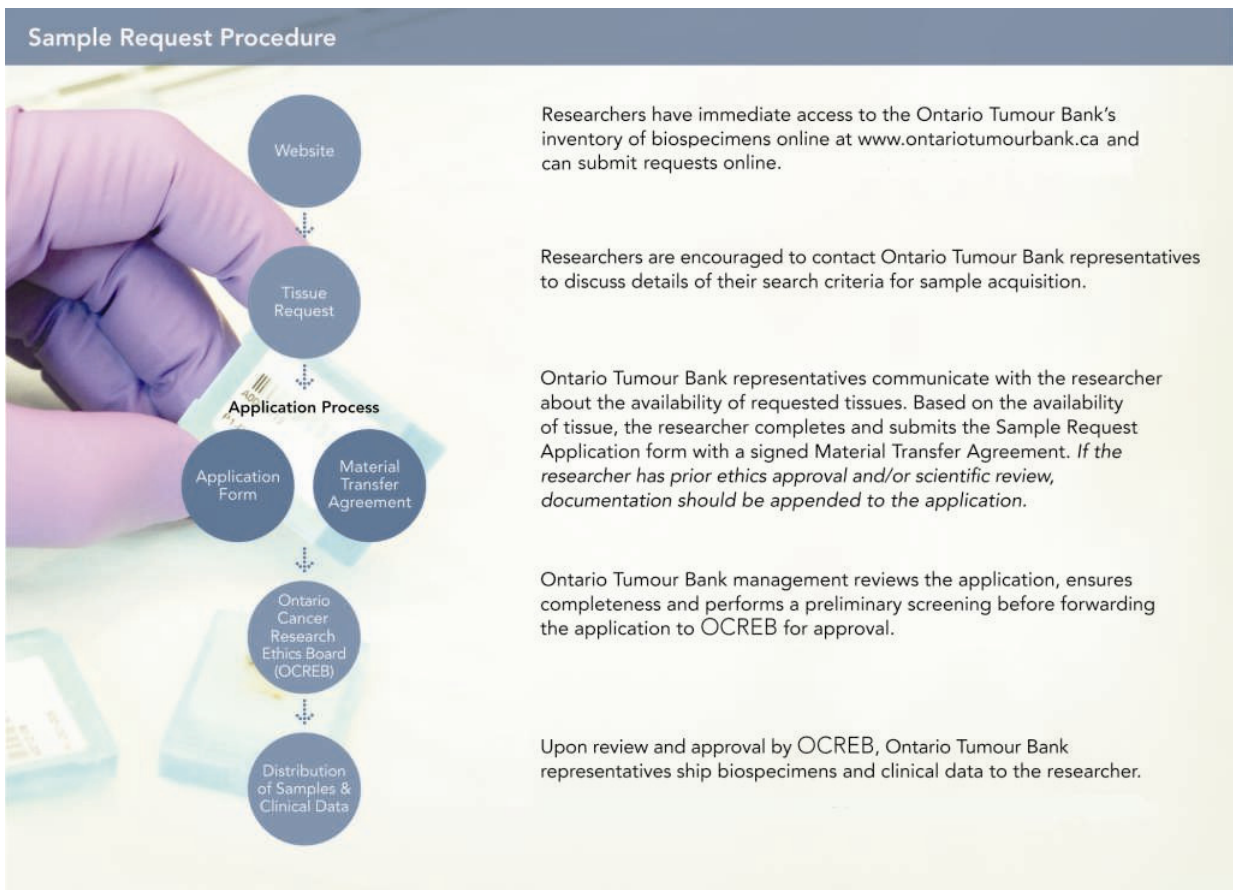
GUIDELINES FOR RESEARCHERS

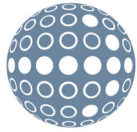
(Updated April 26, 2010)

Request Submissions

The Ontario Tumour Bank (OTB) provides approved researchers with biospecimens and de-identified data from its current inventory. On a case-by-case basis, if the number of samples required is greater than the current inventory, OTB and the applicant may engage in a longer-term relationship and negotiate sample distribution over a period of time.

All requests for samples and data that are submitted to OTB are evaluated by the Ontario Cancer Research Ethics Board (OCREB) in a timely manner. This review and approval of the research ensures that credible researchers are applying for scientifically and ethically-responsible use of the samples and data.





Ethics Considerations

The role of OCREB is to provide a consistent standard for scientific and ethical review of requests for OTB samples and data. OCREB operates according to the *Tri-Council Policy Statement* and the *Health Canada/ICH Good Clinical Practices: Consolidated Guidelines*, Provincial (PHIPA) and Federal (PIPEDA) privacy regulations, and guidance documents such as *CIHR Privacy Best Practice Guidelines*. When approval from another research ethics board is submitted with the application, OCREB also consults this.

Researchers are asked to submit an application which in a maximum of two (2) pages indicates the objective and significance of the research project, along with a brief description of methods. The following are a guideline of the evaluation criteria:

- **Scientific Approach**

Are the conceptual framework, hypothesis, design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Is this a justified and efficient use of the biospecimen resource? Does the application acknowledge potential problem areas and consider alternative tactics?

- **Significance and Applicability**

Does this proposed project address an important problem in the study of cancer? If the aims of the application are achieved, how will scientific knowledge be advanced?

- **Investigator**

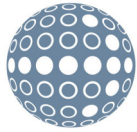
Is the investigator appropriately trained and have the expertise to conduct this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

- **Funding**

Does this proposal have specific funding? Is this funding adequate to perform the proposed work?

- **Ethical Issues**

Do the benefits of the research outweigh any risks to the sources of the tissue, both individual and groups?



Amendment Submissions

What constitutes an amendment?

Any change to the initial application is considered an amendment.

Examples of an amendment may include:

- a) an increase in the number of samples required (*if so, please contact OTB to first enquire about the availability of additional samples*); or
- b) a change in the type of samples required (*if so, please contact the OTB to first enquire about the availability of the samples*); or
- c) a change to the objectives, significance or methods of the research project.

Amendments must be put in writing and should include the following:

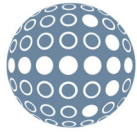
- a) statements describing the amendment; and
- b) the rationale for all proposed amendments.

OTB will forward the amendment to OCREB on the researcher's behalf.

What constitutes a new application submission?

A new application must be submitted if the changes to the initial application are extensive, such as the request is for a new project.

OTB will determine in consultation with OCREB if an amendment is acceptable or whether a new application is needed. OCREB reserves the right to make the final determination.



Approval Process

New Submissions

OTB reviews new applications for completeness before they are forwarded to OCREB for review. OCREB reviews are completed within five (5) business days. OTB will forward OCREB's approval letter to the researcher.

A Material Transfer Agreement also forms part of all submissions to OTB and an application is deemed complete only upon its full execution.

Amendments

Amendments will be reviewed as the need arises.

Annual Renewal

OCREB approval is valid for twelve (12) months from the date of original approval. If the study is still ongoing beyond twelve months, then a request for extended use of the samples and data is required by OCREB. A short progress report, i.e. less than one page summary, describing the progress to date should be submitted, with an indication of the projected closure date for the study.