



## Réseau de recherche sur le cancer du FRSQ

### Réseau de recherche sur le cancer Policy

#### Informed Consent

Policy Number:	POL 01	Category:	Policy
Supercedes:		Effective date	
Subject:	Informed Consent		

### BRIEF INTRODUCTION TO POLICY

The use of human tissue for the purpose of medical research has gained importance in the advancement of knowledge, testing of new therapies and diagnostics and elucidation of disease. Tumour tissue removed in the course of surgical treatment or excess human material left over from diagnostic testing is a valuable research tool. However, the use of human tissue in research; raises ethical issues based on the moral status of human tissue. The access and use of data associated with, or derived from human tissue, is also an ethical issue.

Informed and voluntary consent is a fundamental requirement for ethical research involving human subjects. Consent should be obtained from the participant before its use in medical research, of human materials surplus to clinical requirements. The consent process requires sensitivity to the dignity, cultural notions and physical integrity of the individual participant in the tumor repository program.

### 1.0 PURPOSE

The RRCancer du FRSQ is committed to high ethical standards and practices in the collection and storage of human tissue for research purposes. The purpose of this policy is to outline general principles for best practice that should be used by RRCancer member repositories, in obtaining voluntary and informed consent from the tumor bank participants.

## 2.0 SCOPE

The policy applies to participant consent issues. It outlines best practices for the process of obtaining informed and voluntary consent from the participant, for the acquisition of patient clinical data and tissue material surplus to clinical requirements, specifically for use in medical research.

## 3.0 RESPONSIBILITY

This policy applies to RRCancer member repositories and especially to personnel involved in:

- Developing and adapting of Patient Consent forms
- Providing information to the patient about the Tumour Repository Program
- Obtaining consent from the patient

## 4.0 DEFINITIONS

**Existing or historical collections:** Collections comprising samples that were collected and stored before guidelines such as the Canadian Tri-Council policy Statement; Ethical Conduct for Research Involving Humans, came into operation (August 1998).

**Human Biological Material:** All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.

**Participant:** An individual (patient or healthy volunteer, if applicable) who participates in the Tumour Repository Program. The terms patient, participant, subject and potential donor may be used interchangeably.

**Informed and Voluntary Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in the Tumour Repository Program, after having been informed of all aspects of the program and research that are relevant to the subject's decision to participate.

**Legally Acceptable Representative:** An individual or judicial or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the tumour repository program.

**Research Ethics Board (REB):** An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of

human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants.

## **5.0 POLICIES**

RRCancer member repository personnel should be aware that there are personal sensitivities associated with the donation of tissue and be cognizant of this issue before approaching potential participants. Voluntary and informed consent is a key mechanism for protecting the rights of the participant. Consent encompasses the process that starts with initial contact and carries through to the end of the involvement of the participant in the project.

The following principles should guide the RRCancer member repositories in the process of obtaining consent.

- The collection and use of human tissue for research should be undertaken with free and informed consent of competent participants. Consent should also be obtained to collect or access personal and clinical information from medical records.
- Consent should be obtained voluntarily, without manipulation, undue influence or coercion. It should also be made clear that a participant can revoke consent at any time and that a decision not to participate in the program, will in no way compromise the standards of medical care the patient will receive.
- In the case of incompetent participants, consent should be obtained from an authorized third party (legally acceptable representative).
- Written consent should be obtained.
- When seeking consent, information for participants, legally acceptable representatives, impartial witnesses or an intermediary should be presented in a clear form that can be easily understood. Lack of proficiency in the operating language should not disqualify participants. In this case an intermediary competent in the language should translate the relevant information and the participant should acknowledge in his or her language an understanding of the project, the extent of his or her participation, the risks involved and freely give consent.
- Participants should be aware of financial considerations. It should be made clear that they will not receive any compensation for their participation in the program. If any new tests, discoveries or products with potential commercial

value result from research on their tissue, they will not share in financial benefits.

- Issues of privacy and confidentiality should be discussed with the participant. If relevant, the participant should be informed about identifying information attached to specific tissue and its potential traceability. How this could affect privacy should also be covered. Safeguards to protect the individual’s privacy and confidentiality should be outlined.
- The written informed consent form and any other written information to be provided to the participants should have the written approval/favourable opinion of an appropriate Research Ethics Board (REB). Any revisions to the informed consent form or the written information should receive the REB approval/favourable opinion in advance of use.
- During the consent process participants should also be provided with information about:
  - a. The purpose of the program
  - b. The type and approximate amount of the tissue to be taken
  - c. The manner in which the tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of storage
  - d. The potential uses for the tissue (objectives of research)
  - e. The potential users of the repository (academic and commercial users)
  - f. Potential risks and benefits if any to the participant
  - g. Who will access tissue, personal clinical and research information, what information will be obtained and how the patient’s privacy and confidentiality will be protected
  - h. How surplus material will be disposed of, should it be no longer needed
  - i. Issues of financial benefit

## 6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 01.001	04.11.2005	Original
POL 01.002		Brief description of revision. Sections of SOP affected.

## 7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

1. Declaration of Helsinki. <http://ohsr.od.nih.gov/helsinki.php3>  
<http://www.wma.net/e/policy/b3.htm>

2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. <http://www.ich.org>  
[http://www.ich.org/UrlGrpServer.jsr?@\\_ID=276&@\\_TEMPLATE=254](http://www.ich.org/UrlGrpServer.jsr?@_ID=276&@_TEMPLATE=254)
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations [http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food\\_drug\\_reg\\_amend\\_1024\\_gcp\\_tc\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html)
4. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998. <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
5. USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. <http://www.fda.gov/oc/gcp/default.htm> or [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfe/fr/CFRSearch.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfe/fr/CFRSearch.cfm)
6. Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm>
7. Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004;144:229-34
8. Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. Arch. Intern. Med.2005; 165(1):97-100.