Réseau de recherche sur le cancer du FRSQ

Réseau de recherche sur le cancer Policy Privacy and Security			
Policy Number:	POL 04	Category:	Policy
Supercedes:		Effective Date	
Subject	Privacy and Security		

BRIEF INTRODUCTION TO POLICY

The value of the human biological material (HBM) for research purposes is greatly enhanced by the accompanying personal or clinical data related to the individual providing the sample. Personnel should treat any information about the individual, however derived, as confidential.

Rules protecting the privacy of personal information collected for research purposes are outlined in national research ethics guidelines. Privacy is also protected by several Canadian statutes such as the federal Personal Information Protection and Electronic Documents Act (PIPEDA) and the provincial statutes such as the Personal Health Information Protection Act (PHIPA).

To comply with the guidelines on privacy and confidentiality, participants should be informed about how information about them will be used. Tumour repositories should have each participant's explicit consent to obtain, store and use information about them. Participants should also be aware of what safeguards are in place to protect their confidentiality.

1.0 PURPOSE

The Réseau de recherche sur le cancer du FRSQ (RRCancer) is committed to compliance with national and provincial guidelines and laws safeguarding the privacy and confidentiality of participants that have provided personal and clinical data and tissue samples to the member tumour repositories. The purpose of this

RRCancer policy is to outline general principles to ensure that the privacy of the patient is safeguarded.

2.0 SCOPE

The policy applies to privacy and confidentiality considerations that arise in the conduct of tissue banking research. The issues concern storage, transmission, retention and sharing of participant information in a manner compliant with legislative and ethical requirements.

3.0 RESPONSIBILITY

This policy applies to RRCancer members and to personnel involved in all aspects of the tissue repository program that have access to patient information, samples and research results.

4.0 DEFINITIONS

Custodianship: Responsibility for safe keeping of tissue samples and associated data and control of their use and eventual disposal in accordance with the terms of the consent given by the participant and as regulated by the Research Ethics Board. Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of donors.

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.

Material Transfer Agreement (MTA): A Material Transfer Agreement is a document, which defines terms and conditions attached to the transfer of human biological material and annotated data from one organization to another. In this case it is from the tumour repository to the researcher requesting and receiving HBMs.

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.

Personal information: All information about individuals, living or dead. This included written and electronic records and information obtained from samples.

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

The use of HBM and accompanying data is critical for medical research. The public and participants should have confidence that repositories and researchers will use and handle such material with confidentiality. It is important to ensure that sensitive information is used ethically and optimally for the research to benefit health and knowledge. Safeguarding the privacy of the participants should be of primary importance.

The following set of policies or principles should guide the RRCancer repositories in collecting, maintaining and managing the confidential information it controls:

5.1 Accountability for Personal Information

- Accountability of RRCancer member repositories for compliance to the privacy policy and applicable legislature rests with the repository directors or designated official for day-to-day collection and processing of personal information. The name of the designated official, accountable for overseeing compliance to these principles, should be a matter of public record.

- As the custodian of personal information in its possession, including information that may be transferred to a third party, the repository should use contractual means (such as an MTA) to ensure a comparable level of protection while the information is being used by the third party.

5.2 Identifying Purposes for the Collection of Personal Information

- Personal and medical information and research results relating to the participant and tissue sample should always be treated as confidential. The participant should be made aware of the type of personal and medical information that will be used by researchers.

5.3 Consent for the collection use and disclosure of Personal Information.

- Consent is required for the collection of personal information and the subsequent use and disclosure of this information. The repositories should seek consent for the use or disclosure of the information at the time of collection.

- In keeping with the concept of 'informed consent', the repositories should make an effort to ensure that the participants are advised of the overall purposes for which their information will be used. Participants should be confident that repositories will follow the guidance of the REB for reviewing and approving access to their material.

- Information should not be used for purposes that have not been specifically identified in the consent process without seeking the guidance of the REB.

5.4 Limiting Collection

- The member repositories will not collect personal information indiscriminately. Both the amount and the type of information will be limited to that which is necessary for the purposes identified by the collecting repository in the consent process.

5.5 Limiting Use, Disclosure, and Retention of Personal Information

- Personal information should not be used or disclosed for purposes other than those for which it was collected.

- The repository should control the release of information to researchers by evaluating each request for scientific merit and compliance with approved ethical standards. Researchers using the tumour repository can only use HBMs or disclose information in accordance with the terms and conditions outlined in a Material Transfer Agreement (MTA).

- The local tumour repositories should develop guidelines and implement procedures (approved by the REB) with respect to the retention of personal information:

    - For cases of withheld consent, all case related tissue and data held (electronically or on paper) by the local repository should be removed or destroyed.
    - For cases of revoked consent, all case related tissue and data should be limited or destroyed. Guidance of the REB should be

used in the management of case related tissue and data accrued, that cannot be destroyed as it may already be engaged within a research protocol.

5.6 Accuracy of Personal Information.

- To minimize the possibility that inappropriate or insufficient information may be used to make decisions or conclusions about the research undertaken, personal information and data should be accurate, complete and up-to-date.

5.7 Ensuring safeguards for Personal Information and HBMs.

- The security safeguards should protect HBMs and personal information against loss or theft as well as unauthorized access, disclosure, copying, use or modification. RRCancer repositories should protect personal information and HBMs regardless of the format in which it is stored.

- Security safeguards appropriate to the sensitivity of the personal and clinical information should protect this information.

- Methods of ensuring security of HBMs and associated information should include the following methods:

  a. Physical measures such as locking repository filing cabinets, freezers, fridges and restricting access to offices and laboratories.
  b. Organizational measures, such as limiting access on a 'need-to-know' basis.
  c. Technological measures, such as using passwords, firewalls, and encryption.
  d. Encoding procedures such as de-identification or de-personalization of source data.
  e. Routine back-up of data and information stored electronically.

5.8 Openess About Personal Information Policies and Practices.

- RRCancer repositories should be open about its policies and practices with respect to management of personal information. Participants should be able to acquire information about policies and practices without unreasonable effort and this information should be made available in a form that is generally understandable.

- RRCancer repositories should make information about policies and practices available in a variety of ways. This may include brochures

available at its place of business or at promotional events and online access to policies, forms and selected educational material.

5.9 Individual Access to Own Personal Information.

- Upon written request, a participant should be informed of the existence, use and disclosure of their personal information and upon identity verification should be given access to that information if traceable. The process should be managed under the guidance of the REB.

- Personal information includes data that has been collected (including lifestyle and clinical data) but not data created by research (such as genetic data).

- Exceptions to individual access should be controlled by the REB and may be warranted if the information contains references to other individuals, is prohibitively costly to provide, is not traceable or cannot be disclosed for legal, security or commercial proprietary reasons.

- If valuable medical information becomes available from research on repository samples, the decision to contact the patients or their families to offer benefits of that research, should be guided by the REB and best clinical practice.

5.10 Challenging compliance with RRCancer Privacy policy and practices.

- RRCancer will put procedures into place to receive and respond to complaints or inquiries about its policies and practices relating to the handling of personal information. The procedure should be easily accessible and simple to use.

6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 04.01	04.11.2005	Original
POL 04.02		Brief description of revision. Sections of SOP affected.

7.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. 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
3. 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
4. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
5. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws.justice.gc.ca/en/p-8.6/93196.html
6. Ontario's Personal Health Information Protection Act http://www.ontla.on.ca/documents/Bills/38_Parliament/Session1/b031ra_e.htm
7. Alberta's Freedom of Information Protection of Privacy Act http://www.oipc.ab.ca/home/
8. Alberta's Health Information Act. http://www.oipc.ab.ca/home/
9. British Columbia's Freedom of Information Protection Act. http://www.oipc.bc.ca/legislation/FOI-ACT%20(2004).pdf
10. Manitoba's Freedom of Information and Protection of Privacy Act (FIPPA) and Personal Health Information Act (PHIA) http://www.ombudsman.mb.ca/access.htm
11. Quebec's Act respecting access to documents held by public bodies and the protection of personal information. http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/A_2_1/A2_1_A.html
12. American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility. 2003. J. Clin. Oncol. 21(12):2397-2406.