Réseau de recherche sur le cancer du FRSQ

Réseau de recherche sur le cancer Records and Documentation			
Policy Number:	POL 05	Category:	Policy
Supercedes:		Effective Date	
Subject:	Records and Documentation		

BRIEF INTRODUCTION TO POLICY

Recent developments in molecular biology and genomics have essentially enhanced the value of clinically annotated human tumour tissue in translational research and drug discovery. Adherence to best practices in the generation and maintenance of complete and accurate documentation is important in ensuring the value and utility of resources within the tumour repository. For translational research to progress into practice via a commercial route, intellectual property rights (IPR) should be protected. IPR can only be protected adequately if all records and documents are thorough, accurate and contemporaneous.

1.0 PURPOSE

The Réseau de recherche sur le cancer du FRSQ (RRCancer) is committed to high ethical, scientific and operational standards and practices in the collection and storage of human tissue for research purposes. The generation of clear, accurate, comprehensive and retrievable records and documents are vital to the repositories compliance and success. The purpose of this RRCancer policy is to outline general principles that can be used by repositories to ensure that records and documents are maintained with common essential standards.

2.0 SCOPE

The policy applies to all records and documents that have to be generated and maintained as part of the operation of the tumour repository. The policy covers written (notebooks), original paper records, true copies such as photocopies, microfiche or microfilm as well as electronic records and documents.

3.0 RESPONSIBILITY

As custodians of HBMs and associated information, repositories have an ethical responsibility to maintain complete and auditable records. This policy applies to RRCancer member repositories and to personnel involved in generating, maintaining and managing records and documents within the tissue repository program.

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.

Digitization: Creating digitized images from glass slides (e.g. using a digital camera mounted on a microscope).

Encoded Samples: have a coded identification to protect the confidentiality of the individual during routine use, but it is possible for the repository to break the code and thus identify the individual from whom they were obtained.

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.

Intellectual Property: A product of research or intellect that has commercial value, including discovery patents, research methods, and industrial processes.

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.

Translational Research: Integrated clinical-laboratory investigations designed to improve the prevention, diagnosis and/or treatment of disease. Involves both clinical and laboratory investigations, or laboratory investigations on clinical material.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the Tumour Repository Program is performed and the

data are generated, documented (recorded), and reported in compliance with applicable regulatory requirement(s).

5.0 POLICIES

The use of HBMs and accompanying data is critical for medical research. Clear, accurate and complete records are essential to any research program. As custodians of samples of HBMs, repositories are responsible for keeping proper records. The following principles should guide the RRCancer repositories in maintaining compliant records and documents.

5.1 Collecting and managing information and data

- Confidentiality of personal information as well as data associated with tissue and biological samples is essential. All personal information must be encoded as early as possible after collection.

- Data records should be monitored to ensure completeness and accuracy.

- Custodians of HBMs are responsible for keeping proper records of all uses that have been made of the material, whether by themselves or by others.

- Custodians of HBMs should ensure that all uses have appropriate Ethics Review Board approval, and keep copies of such approvals for easy reference.

- When linked encoded samples are provided to a third party, the custodian is responsible for safe keeping of the code enabling samples to be linked to individual donors.

5.2 Retaining information and data

- Retention of accurately recorded and retrievable information, data and results are essential for the running of a tumour bank and should be retained indefinitely to be of value to translational researchers.

- Researchers (who are leaving an establishment) that generated data and who wish to retain data/copies of data for future use must get specific permission to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the consent and contract with that researcher.

5.3 Retention of Data in the Case of Withheld or Revoked Consent

Publication of data imposes a requirement that researchers and the local repository retain source data or records.

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

- For cases of revoked consent, all case related information 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.

5.4 Notebooks and Electronic Records

- All raw data or personal and clinical information should be recorded and retained in laboratory notebooks or in an electronic database dedicated to that purpose.

- Machine print-outs, consent forms, questionnaires, chart recordings, autoradiographs, forms etc. which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross-indexed with the main record.

- Notebook and electronic records should be entered as soon as possible after the data is collected or generated. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should be clearly identified and dated.

- There should be processes in place for quality assurance of data collected and recorded electronically.

- Digitized data/images should be recorded and retained in a “raw” or original format as well. This is especially relevant where data/images undergoing digitization are subsequently enhanced. If possible, both the original and enhanced forms should be stored.

- Electronic records should be backed-up regularly; duplicate copies should be held on disc in a secure but readily accessible archive.

5.5 Personnel and Users Access to Information and Records

- Access to data should be given to users on a 'need to know' basis. Users should be granted access to specific data records that they need to access to in order to perform their duty. This access should be removed when the activity is completed.

5.6 Transmission of Information and Data

- Information from incoming sources (such as regional collection sites and TBCD member repositories) should be transmitted in a secure manner.

5.7 Physical Storage of Information and Data

- Data and records should be stored securely and with appropriate contingency plans.
- Data and records should be stored in a manner to permit retrospective audit if needed.
- Records and back-up discs should be stored to maximize protection from factors such as flooding, fire or theft.

6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 05.01	04.11.2005	Original
POL 05.02		Brief description of revision. Sections of SOP affected.

7.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
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. 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

4. Medical Research Council, Ethics Series. Good Research Practice
http://www.mrc.ac.uk/pdf-good_research_practice.pdf

5. Good Laboratory Practice for nonclinical lab studies (CFR21-Chapter1 Part 58 Subpart J (58.185, 58.190 and 58.