Réseau de recherche sur le cancer du FRSQ

Réseau de recherche sur le cancer Policy

Material and Information Handling

Policy Number	POL 07	Category:	Policy
Supercedes:		Effective Date	
Subject:	Material and information handling		

BRIEF INTRODUCTION TO POLICY

Translational research using advances in molecular biology and archived tissue samples and annotated data is set to aid in the elucidation of the disease process and discovery of new treatment modalities. A collection of well stored and well annotated tissue specimens and derivatives is a valuable resource, important to the research process.

The quality and of the samples and extent of the accompanying data is a determinant of value. The goal of the Réseau de recherche sur le cancer du FRSQ (RRCancer) is to standardize procedures for handling samples and data thus ensuring that the quality and integrity of the collection is consistently maintained at a high level.

1.0 PURPOSE

The RRCancer is committed to high ethical standards and practices in the collection and storage of Human Biological Materials (HBMs) and accompanying information for research purposes. The purpose of this RRCancer policy is to outline general principles that can be used to ensure that HBMs and data are handled and stored in a manner sensitive to the rights of the participant, responsible to the safety of repository personnel and protective of the quality and integrity of the collection.

2.0 SCOPE

The policy applies to operational and practical considerations that arise in the process of collecting storing and maintaining tissue samples and annotated data.

The policy is intended to ensure that the goals of the repository network are met and quality and value of the collection is maintained.

3.0 RESPONSIBILITY

This policy applies to RRCancer member repositories and to repository personnel involved in all aspects of the tissue repository program. In particular, it applies to those personnel involved in processing, storing and in any way handling tissue, derivative products or accompanying data.

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.

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.

Researcher: A scientist or clinician from an academic institution or commercial enterprise such as a biotechnology or pharmaceutical company who is involved in a laboratory and/or clinical research project and is interested in obtaining material from the tumour repository for research purposes. The term ‘user’ may be used interchangeably.

Storage: Maintenance of specimens for future use.

Translational Research: Integrated clinical-laboratory investigations designed to improve the prevention, diagnosis and/or treatment of cancer. 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 Bank Program is performed and the data are generated, documented (recorded), and reported in compliance with applicable policies, procedures and regulatory requirement(s) if any.

5.0 POLICIES

The use of HBMs 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 sensitivity, responsibility and concern for maintaining the value of the collection. The following principles should guide the RRCancer repositories in collecting, processing and storing tissue and information in its custody.

5.1 Material handling –General Considerations

TBCD aims to provide users of the tissue repository standardized, high quality biological samples that are readily accessible for their research needs.

- To meet the needs of the users the HBMs should be collected, processed and stored in a manner that optimally maintains the architecture of the tissue and the molecular integrity of the DNA, RNA and proteins in the specimens.
- All steps should be performed by staff that are suitably qualified or have adequate training to perform the tasks.
- Established standard operating procedures should be in place for all procedures involved in collection, processing, storing and retrieving HBMs and annotated information at the repositories.
- Laboratory equipment and infrastructure should be appropriate to ensure proper collection, storage, processing, quality control and distribution.
- Computer/Informatics infrastructure should be appropriate to enable each repository to collect, store and share data in an efficient and secure method.
- Quality Assurance procedures such as routine audits and quality control analysis should be performed to ensure that integrity and quality of the collection is maintained.

5.1.1 Tissue Collection

- Tissue for the repository should be obtained only after all patient diagnostic needs have been met and should be accompanied by documented, informed consent.

- Tissue samples should be collected from a wide range of patients (with participant matched normal specimens whenever possible). The collection process should attempt not to exclude a sub-set of the patient population. If possible, specimens should be collected in sufficient quantity and diversity to be of value in a variety of study designs.

- Broader molecular profiles can be obtained from samples that have been collected using rigorous and standardized procedures. Collection procedures should be geared to allow use of the samples in genomic and proteomic research.

- To ensure suitability for genomic and proteomic research the time elapsed between surgical resection of the tumour and freezing should not exceed 30 minutes. Adequate documentation should capture this parameter for quality assurance purposes.

5.1.2 Tissue Processing

- To ensure suitability for genomic and proteomic research the processing of the tissue sample or blood should be done in a manner to protect tissue architecture and the integrity of molecular products.

- HBMs should be handled as being potentially biohazardous and lab staff should take appropriate precautions when handling tumour tissue or whole blood and blood products

- Desiccation and degradation of specimens should be avoided. The method of transport of the tissue sample from the operating room to the pathology or processing lab should be documented. Suitable methods include insertion of the specimens into a container (such a plastic bag) and immersion in anice-saline slurry.

- All precautions to avoid cross-contamination of specimens during processing, product isolation or aliquoting should be employed. This should include using fresh containers, pipette tips and blades between specimens and between different areas of the same specimen (i.e. between malignant and associated uninvolved tissue).

- Snap freezing or freezing in a cryoprotectant should be done in liquid nitrogen or dry ice in a timely manner and procedure should focus on avoiding ice crystal formation or disruption of cellular architecture.

- Specimens in the collection are useless if incorrectly identified. Optimally, all samples should be appropriately labeled using a system compatible across the network.

5.1.3 Tissue Storage and Retrieval

The storage method of the tissue sample or derived product affects the suitability of the sample for use in specific genomic or proteomic studies

- Storage procedures should be geared to protecting the integrity of the collection and allowing for efficient and accurate retrieval of samples.

- Samples should be sored in a manner optimal for their intended category and use. This should be documented.

- Frozen samples should be stored in a screw-capped, plastic containers or cryovials that can be sealed. Vials should permit appropriate labeling, prevention of contamination or sample dessication and should withstand freezing in liquid nitrogen.

- If mechanical or liquid nitrogen systems are used for storage of frozen samples, adequate back-up capacity should be maintained to ensure that operating temperatures are maintained at all times. Events such as equipment failure or power-outage emergency should be planned for.

- Processes should be in place to deal with possible emergencies.

- For mechanical freezers, manual defrost feature is optimal as freeze-thaw cycles of automatic units can degrade biologic samples.

- Ideally, alarm systems should be used to monitor temperatures in the storage freezers and procedures should be in place to permit corrective action before the temperatures fall out of range.

- Proper procedures should be followed for sample retrieval to ensure that proper conditions are maintained to protect the sample, and that documentation is completed to record any change in inventory.

- Shipping and transportation procedures should be established to ensure that containers, labels, conditions and methods are optimal for sample protection

- Tracking and life-management of HBMs is critical. A high quality inventory should be employed so that every sample can be tracked and audited. All records pertaining to sample retrieval, use or removal should be maintained to facilitate tracking.

5.2 Informatics – Collection and Handling

- Annotated data (clinical, lifestyle, pathological and research generated) should be accurate, quality-controlled and standardized as far as possible.

- Data collected should contain common data elements including:

    - Personal, lifestyle and family history
    - Longitudinal clinical and diagnostic information
    - Treatment and outcome information

- Sample information
- Other data that may be local repository specific such as: lifestyle and family history

- Computerized inventory and bioinformatics systems used to handle and store annotated data should:

  - Be responsive to the needs of multiple users
  - Be available for a long period of time
  - Use standardized terms to categorize specimens and enter data, across member repositories
  - Use an automated data extract system or permit multiple checks of data entry to ensure accuracy
  - Have the ability to feed standard research results and genomic and proteomic results back into the system
  - Allow for dissemination of information to others as needed
  - Be searchable via varying levels for certified users.
  - Provide security and access control to ensure privacy rights are protected
  - Have a tracking function to facilitate stock assessment
  - Support integration and expansion if needed
  - Have maintenance features and back-up capabilities

5.3 Safety considerations

All personnel coming in contact with HBMs or involved in the operations of the tumour repository should be trained in safety procedures to minimize injuries to them and to protect the material and information held in the repository. Safety training should be:

- Given to staff before they begin their work
- Updated as needed
- Lead by knowledgeable trainers
- Appropriate for the background of each employee and to the risks to which each employee is exposed

- Relevant personnel should handle all HBMs as being biohazardous.

- The use of liquid nitrogen and dry ice poses specific safety problems. Appropriate gloves, a face shield and a protective garment should always be used when handling these materials. When dry ice is used, controls to ensure sufficient air and oxygen levels should be ensured.

- Precautions should be taken to minimize risks to injury and damage from biological, chemical, physical, electrical hazards and fire.

- Written guidelines should be developed to ensure safety precautions based on national, regional and local regulations.

- Personnel coming in contact with patients and patient information should be trained in maintaining privacy and confidentiality.

- Overall repository security should be implemented by limiting access to the workplace by unauthorized personnel.

6.0 POLICY HISTORY

SOP Number	Date Issued	Summary of Revisions
POL 07.01	04.11.2005	Original
POL 07.02		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. 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. Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws.justice.gc.ca/en/p-8.6/93196.html
5. Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). http://www.isber.org
6. UKCCSG Guide to Biological Studies Version 1.0, 2002 http://www.ukccsg.org/hp/biological_studies/webguideBs.html

7. US National Biospecimen Network Blueprint
http://www.ndoc.org/about_ndc/reports/NBN_comment.asp

8. Qualman, SJ. et al. Establishing a tumour bank: banking, informatics and ethics. Br. J. Cancer (2004). 90-1115-1119.