CTRNet Policy Material and Information Handling			
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Approved By:	CTRNet Management Group (CMG)	08-Feb-2013
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1.0 INTRODUCTION

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

The quality of the samples and the extent of the accompanying data is a determinant of value. The goal of the Canadian Tumour Repository Network (CTRNet) 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.

2.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/glossary

3.0 PURPOSE

The Canadian Tumour Repository Network (CTRNet) is committed to promoting and educating biobanks to ensure adherence 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 CTRNet 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 biobank personnel and protective of the quality and integrity of the collection.

4.0 SCOPE

This policy applies to the operational and practical considerations that arise in the process of collecting, storing and maintaining tissue samples and annotated data. The policy in intended to ensure that the goals of the biobank network are met and that the quality and value of the collection is maintained.

5.0 RESPONSIBILITY

This policy applies to CTRNet member biobanks and to biobank personnel involved in all aspects of the tumour biobank program. In particular, it applies to those personnel involved in processing, storing and handling tissue, derivative products and/or accompanying data.

6.0 POLICIES

The use of HBMs and accompanying data is critical for medical research. The public and participants should have confidence that biobanks 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 CTRNet biobanks in collecting, processing and storing tissue and information in its custody.

6.1 Material handling – General Considerations

CTRNet aims to provide users of the tumour biobank standardized, high quality biological samples that are readily accessible for their research needs.

a) 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.

b) All steps should be performed by staff that are suitably qualified or have adequate training to perform the tasks.

c) Established standard operating procedures (SOPs) should be in place for all procedures involved in collection, processing, storing and retrieving HBMs and annotated information at the biobanks.

d) Laboratory equipment and infrastructure should be appropriate to ensure proper collection, storage, processing, quality control and distribution.

e) Computer/Informatics infrastructure should be appropriate to enable each biobank to collect, store and share data in an efficient and secure method.

f) Quality Assurance (QA) procedures such as routine audits and quality control analysis should be performed to ensure that integrity and quality of the collection is maintained.

6.1.1 Tissue Collection

a) Tissue for the biobank should be obtained only after all patient diagnostic needs have been met and should be accompanied by documented, informed consent or a waiver of consent from the relevant Research Ethics Board (REB).

b) Tissue samples should be collected from a wide range of patients (with 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.

c) 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.

d) To ensure suitability for genomic and proteomic research the time elapsed between surgical resection of the tumour and freezing ideally should be rapid to ensure preservation. Adequate documentation should capture the timeframe for quality assurance purposes.

6.1.2 Tissue Processing

a) 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.

b) HBMs should be handled as being potentially biohazardous and laboratory staff should take appropriate precautions when handling tumour tissue or whole blood and blood products.

c) 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 laboratory should be documented.

d) 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 (e.g. between malignant and associated uninvolved tissue).

e) Snap freezing or freezing in a cryoprotectant should be done by suitable means.

f) Specimens in the collection are useless if incorrectly identified. All samples should be accurately labeled.

6.1.3 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.

a) Storage procedures should be geared to protecting the integrity of the collection and should allow for efficient and accurate retrieval of samples.

b) Samples should be stored in a manner optimal for their intended category and use. This should be documented.

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

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

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

f) 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 falls out of range.

g) 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.

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

i) Tracking and auditing 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.

6.2 Informatics – Collection and Handling

6.2.1 Annotation data (e.g. person, lifestyle, diagnosis, laboratory, clinical and research generated) should be accurate, quality-controlled and standardized as far as possible.

6.2.2 Data collected may contain common data elements from the following categories including, for example:

a) Personal

b) Longitudinal clinical and diagnostic information

c) Treatment and outcome information

d) Sample information

e) Lifestyle and family history

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

a) Be responsive to the needs of multiple users

b) Be available for a long period of time

c) Use standardized terms to categorize specimens and enter data, across member biobanks

d) Use an automated data extract system or permit multiple checks of data entry to ensure accuracy

e) Have the ability to feed back or link standard research results and genomic and proteomic results into the system

f) Allow for dissemination of information to others as needed

g) Be searchable at varying levels for certified users

h) Provide security and access control to ensure privacy rights are protected

i) Have an inventory management system

j) Support integration and expansion if needed

k) Have maintenance features and back-up capabilities

6.3 Safety Considerations

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

a) Given to staff before they begin their work

b) Updated as needed

c) Lead by knowledgeable trainers

d) Appropriate for the background of each employee and to the risks to which each employee is exposed

6.3.1 Relevant personnel should handle all HBMs as being biohazardous.

6.3.2 The use of liquid nitrogen and dry ice poses specific safety hazards. 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.

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

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

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

6.3.6 Overall biobank security should be implemented by limiting access of unauthorized personnel to the workplace.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

7.1 Declaration of Helsinki.
http://www.wma.net/en/30publications/10policies/b3/index.html

7.2 Tri-Council Policy Statement 2; 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, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/.

7.3 Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics Series.
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

7.4 UKCCSG Guide to Biological Studies Version 1.0, 2002

7.5 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

7.6 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

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

7.8 Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 007.001	Feb 2006	JDSH	Original document
POL 7 e1.1	Apr 2009	P. Geary	Updated format. Revised numbering.
POL 7 e2.0	Feb 2013	CMC	• Reviewed and revised by CTRNet Management Committee • Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates