CTRNet Standard Operating Procedure Document Quality and Care			
SOP Number:	3.1.008	Version	e1.0
Supersedes:		Effective Date	09 Jan 08
Subject:	Document Quality and Care	Category	Records Management and Documentation

Prepared By:		Jean de Sousa-Hitzler		
	Signature	Name	Title	ddMmmyy
Approved By:		Peter Geary	CEO	09 Jan 08
	Signature	Name	Title	ddMmmyy
Approved By:				
	Signature	Name	Title	ddMmmyy

REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
31.008	2008	JdSH	1st Release.

1.0 PURPOSE

1.0 PURPOSE

The Canadian Tissue Repository Network (CTRNet) is committed to high standards for quality assurance and operational practices in the collection and storage of human tissue for research purposes. Systems should be in place to track samples from the site at which they are collected through their arrival and subsequent shipping from the tumour bank at which they are stored. Labels should identify the samples as they are collected, transported, processed and stored. Tracking should log samples as they are collected, processed, transported, stored and released from the tumour bank. An inventory system should permit repository staff to locate a sample within a repository at all times from collection to release. The purpose of this CTRNet Standard Operating Procedure (SOP) is to outline general procedures that can be used by repositories to ensure that samples are labelled and tracked efficiently.

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

2.0 SCOPE

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

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 002.001 Ethics
3. CTRNet Policy: POL 004.001 Privacy and Security

4.0 ROLES AND RESPONSIBILITY

This SOP applies to CTRNet members and to repository personnel involved in generating, maintaining and managing records and documents within the tissue repository program. Roles and responsibilities may vary at specific sites.

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank Director, Manager, Coordinator	Ensures adequate documentation and maintenance of records	
Lab Technincian	Documents all processing of specimens	
Tumour Bank Analyst, Records Manager	Audits records, maintains updated computer records	

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	**Materials and Equipment (Site Specific)**
Record Management System	
Computers	

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

6.0 DEFINITIONS

Audit Trail: Documentation that allows reconstruction of the course of events that occurred before, during and after the conduct of a collection, storage and release of a tumour sample and associated information.

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).

Documents: Documents which individually and collectively permit evaluation of the conduct and compliance of tumor repository program and the quality of the information collected and generated.

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.

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.

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.

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

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).

7.0 PROCEDURES

Maintaining well-organized, complete and accurate documentation of all tumour repository activities is vital to the operation of a successful tumour bank. Timely collection and filing of all required documents also assists in the efficient management of tissue samples and information.

All records must be accurate, indelible, legible and retrievable.

7.1 General Principles for Organization of Study Files

1. Create a logical, organized filing system that allows for rapid retrieval of program documents.
2. Store essential documents (Attachment 1) in a binder or file box in a secure location (e.g., a locked cupboard of file cabinet). *Add institutional storage specifics.*
3. Protect the confidentiality of all participant records (e.g., recruitment logs, Informed Consent Forms) and store in a secure location.
4. Create a separate reference binder to store documents, SOPs, Policies, published papers etc. Store SOPS so that they are easily accessible to relevant personnel.
5. Routinely update all documents to reflect current information and status.
6. Archive all documents relating to consented participants as required by the REB and /or scientific needs.

7.2 Participant File Creation and Maintenance

1. Open a participant file soon after patient recruitment.
2. File new documents on an ongoing basis. *(Indicate those responsible for ensuring that items are filed appropriately and files are up-to-date)*
3. Prior to making any modifications, deleting or destroying any documents, obtain approval from someone in a supervisory role at the repository. Document all changes and actions performed on the document.

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

7.3 Document Standardization (Common terms and data elements)

1. Use common terms to coordinate operations such as exchange of data, reporting and checks of accuracy.
2. Maintain records, policies and procedures in a standardized format.
3. To promote the use of common terms and formats, implement the use of drop down menus and document templates where possible.
4. Generate and circulate lists of definitions, commonly used terms and update as relevant.

7.4 Document Standardization (Signatures)

1. Use legal names for signatures.
2. Do not use initial for last name.
3. Use ink for all signatures
4. Signatures must be dated by each person signing the form (do not complete date for another signer).

7.5 Document Standardization (Recording date and time)

1. Record time based on a twenty four hour clock. Time is recorded by four digits. The first two digits represent the hour, the following two digits represent minutes.

2. The twenty four hour clock runs as follows: 0100 through 2400 hours with 0100 representing 1.00 AM and 2400 representing midnight. Minutes are recorded from one to fifty nine.

3. Record dates using a consistent format.

7.6 Document Storage

1. Store hard copies of approved documents so as to protect them from environmental damage and protect privacy of participants. The use of locked fireproof cabinets and rooms is recommended.

7.7 Document Destruction Procedure

1. Paper documents requiring destruction will be passed through a paper shredder before disposal in the general garbage.
2. Electronic documents should be deleted in a secure manner.

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

8.0 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 58.195)

9.0 APPENDICES

1. Essential Documents for Conduct of Tumour repository program

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

APPENDIX 1
ESSENTIAL DOCUMENTS FOR CONDUCT OF TUMOUR REPOSITORY PROGRAM

	Signed agreement between participants, e.g.: • Collecting Institution and Repository • Informed Consent Forms signed by patient, or legal representative if relevant • Informed Consent Form section signed by interpreter or witness if relevant
	Dated, documented approval/favourable opinion of REB of the following: • Informed consent form(s) • Any other written information to be provided to the participants (e.g., questionnaires) • Any other documentation given approval/favourable opinion
	REB Processes • Signed REB Approvals • Signed REB renewals • Committee composition (current)
	Personnel Records • Confidentiality Disclosure Agreements (CDAs)* • Curriculum vitae, resume and/or other relevant documents evidencing qualifications of investigator(s) and other tumour repository personnel* • Personnel Training Records* * Optional, as needed to meet provincial and institutional requirements)
	Medical/ laboratory/technical procedures/tests (where required) • Deviations from procedures for any particular tissue sample • Established quality control and/or external quality assessment or • Other validation (where required) • Records relevant to blood processing and tissue processing • Location and storage conditions for tissue samples and products.
	Guidelines and Procedures • SOPs • Policies
	Material Release Documentation • Material requests from researchers • REB approval for release • Material transfer agreements (signed copies)

Copyright©2008 Canadian Tumour Repository Network (CTRNet).

	• Shipping records and documents

Copyright©2008 Canadian Tumour Repository Network (CTRNet).