CTRNet Standard Operating Procedure Document Maintenance			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	31-May-2012

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 document all activities of the biobank.

2.0 SCOPE

This standard operating procedure (SOP) covers processes for maintenance of all written (notebooks), original paper records, true copies such as photocopies, microfiche or microfilm as well as electronic records.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 2 Ethics*
3.2 *CTRNet Policy: POL 4 Privacy and Security*
3.3 *CTRNet Standard Operating Procedure: SOP 03.001 Information Access Control*
3.4 *CTRNet Standard Operating Procedure: SOP 04.001 Physical Security at Facilities*

4.0 ROLES AND RESPONSIBILITIES

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

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank Manager or Director, Principal Investigator	Ensures adequate documentation and maintenance of records
Laboratory Technician/Technologist	Documents all processing of specimens
Tumour Biobank Analyst, Records Manager	Audits records, maintains updated computer records
Clinical Research Nurse, Laboratory Technician/Technologist, designate (may be admin assistant, research assistant)	Documents clinical activities pertaining to participation in the tumour biobank. May be responsible for archiving 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	
Office storage / filing materials	

6.0 DEFINITIONS

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

7.0 PROCEDURES

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

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

7.1 General Principles for the Management of Study Files

7.1.1 Create a logical, organized filing system that allows for rapid location and retrieval of program documents. Ensure that any electronic system is searchable.

7.1.2 Store essential hard copy documents in a binder or file box in a secure location (e.g., a locked cupboard or file cabinet). The security of electronic data is covered by *CTRNet SOP 03.001 Information Access Control*.

7.1.3 Protect the confidentiality of all participant records (e.g., recruitment logs, Informed Consent Forms) and store in a secure location.

7.1.4 Create a separate reference binder to store documents, SOPs, Policies, published papers etc. Ensure only the most recent SOP versions are easily accessible to the relevant personnel to avoid confusion with previous versions.

7.1.5 Routinely update all documents to reflect current information and status. Archive all documents relating to consented participants as required by the REB and /or scientific needs.

7.2 Participant File Creation and Maintenance

7.2.1 Ensure that all personnel are trained in the use of the filing system.

7.2.2 Open a participant file soon after patient recruitment.

7.2.3 File new documents on an ongoing basis.

7.2.4 Prior to making any modifications, deleting or destroying any documents, obtain approval from someone in a supervisory role at the biobank. Document all changes and actions performed on the document.

7.3 Document Standardization (Common terms and data elements)

7.3.1 Maintain records, policies and procedures in a standardized format. Ensure that the standardization is homogeneous throughout all documentation.

7.3.2 To promote the use of common terms and formats, implement the use of drop down menus and document templates where possible.

7.3.3 Generate, circulate and make accessible all lists of definitions and commonly used terms. Update as relevant.

7.4 Document Standardization (Signatures)

7.4.1 Use full legal names for signatures.

7.4.2 Use ink for all signatures.

7.4.3 Ideally, each person signing the form should date signatures.

7.5 Document Standardization (Recording date and time)

7.5.1 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.

7.5.2 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.

7.5.3 Record dates using a consistent format throughout all documentation.

7.6 Document Storage

7.6.1 Store hard copies of approved documents according to institutional policy. It is recommended to store documents so as to protect them from loss or damage such as environmental damage (e.g. moisture, fire) or misadventure. Also see *CTRNet SOP 04.001 Physical Security at Facilities.*

7.7 Document Destruction Procedure

7.7.1 Paper documents with sensitive information requiring destruction will be passed through a paper shredder before disposal in the general garbage.

7.7.2 Electronic documents should be permanently deleted and non-retrievable.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
http://www.ich.org/products/guidelines.html

8.2 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/

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

8.4 Medical Research Council, Ethics Series. Good Research Practice
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415

8.5 Good Laboratory Practice for nonclinical lab studies (CFR21-Chapter1 Part 58 Subpart J (58.185, 58.190 and 58.195)

9.0 APPENDICES

9.1 Appendix A: Suggested Essential Documents for Conduct of Tumour Biobank Program

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
3.1.008	2008	JdSH	1st Release.
3.1.008		AS	Throughout: grammatical changes Section 6: updated definition of audit trail Section 7.4: Improved sentence related to SOP accessibility
3.1.008 e1.1	May 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 1: Revised second sentence and deleted remainder of paragraph. • Section 2: Combined sentences to include processes for maintenance of all records. • Section 3: Added SOP References 3.1.001 and 4.1.001 • Sections 4 & 5: Additions to content • Sections 7.1 - 7.7: Procedural revisions for accurate documentation and efficient systems management.

SUGGESTED ESSENTIAL DOCUMENTS FOR CONDUCT OF TUMOUR BIOBANK PROGRAM

	Signed agreement between participants, e.g.: • Collecting Institution and Biobank • 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) • Annual updates and ongoing amendments
	Personnel Records • Confidentiality Disclosure Agreements (CDAs)* • Curriculum vitae, resume and/or other relevant documents evidencing qualifications of investigator(s) and other tumour biobank 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 • Privacy Impact Assessments
	Material Release Documentation • Material requests from researchers • REB approval for release / Tissue Distribution Committee approval for release • Material transfer agreements (signed copies) • Shipping records and documents