CTRNet Standard Operating Procedure Administration of Standard Operating Procedures			
SOP Number:	01.005	Version:	e2.1
Supersedes:	01.005 e2.0	Category:	Administration

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	11-June-2012

1.0 PURPOSE

Standard Operating Procedures (SOPs) are detailed written descriptions of how to execute a particular procedure or method. SOPs are based on national and international guidelines and conventions as well as policies and procedures that are considered "best practice" for the Canadian Tumour Repository Network (CTRNet) member biobanks.

The purpose of having documented SOPs is to:

- Provide written guidelines for aspects of the CTRNet tumour biobank program.
- Promote quality and consistency in tumour biobanking and data collection across the CTRNet member biobanks.
- Ensure compliance with applicable regulations and guidelines.
- Facilitate education and training of biobank personnel.

2.0 SCOPE

This Standard Operating Procedure (SOP) describes the processes for the development, review, approval and maintenance of all CTRNet written SOPs. It applies to all tumour biobank personnel involved in writing, revising, reviewing, approving and maintaining SOPs.

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 5 Records and Documentation*
3.2 *CTRNet Policy: POL 3 Education and Training*
3.3 *CTRNet Standard Operating Procedure: SOP 07.001 Education and Training*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all tumour biobank personnel involved in writing, revising, reviewing, approving and maintaining SOPs.

Tumour Biobank Personnel	Responsibility/Role
Consultant	Writing, Revising and updating technical and organizational SOPs
Laboratory Technician/Technologist Assistant/Clinical personnel	Writing, Revising and updating technical SOPs
Tumour Biobank Manager	Writing, Revising and updating organizational and administrative SOPs
SOP Review team	Reviewing, Revising and updating technical and organizational SOPs

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)
SOP Format document	

6.0 DEFINITIONS

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

7.0 PROCEDURES

SOPs are controlled documents designed to give instructions for performing routine and essential processes, to ensure that they are performed consistently and in a manner upholding CTRNet program quality and integrity.

7.1 Developing New SOPs or Revising Previously Issued SOPs

7.1.1 CTRNet, management at the regional biobanks or biobank personnel can identify the need for new/revised SOPs. The need can arise from the findings of a routine SOP review or from changes to regulations, guidelines, research practice, or institutional policies.

7.1.2 Individuals well versed with the procedures or methods being described should be recruited to draft or assist in drafting a new or revised SOP.

7.1.3 The SOP should follow the standard format (see SOP template, Appendix A); the word “draft” should be added to the header. For major revisions to previous SOPs, the major SOP version number must be incremented by one (e.g., 1.0 becomes 2.0). For minor revisions to previous SOPs, the minor version number must be incremented by 1(e.g. 1.0 becomes e1.1). The first version of an SOP is always 1.0.

7.1.4 Develop/revise associated attachments, as applicable and revise the version date.

7.1.5 Update the SOP index (see Attachment B) as necessary (e.g., for new SOPs added).

7.2 Review and Approval of SOPs

7.2.1 Circulate the draft SOP to the applicable reviewers (SOP working committee, management at local biobanks, biobank personnel, and other identified staff representatives – e.g., SOP users) for comments.

7.2.2 Incorporate the comments, revise the draft version date and circulate the revised draft SOP to the biobank Director or designate.

7.2.3 Review the final draft SOP for accuracy and completeness and for compliance with regulations, guidelines and standard practice. In some circumstances, this may involve REB approval of amendment. Also, should note whether change in SOP will require amendment to other administrative documents, especially any applicable Privacy Impact Assessments.

7.2.4 Obtain approval (from a SOP authorized signatory) of the final SOP.

7.2.5 Add the effective date to the front page (the date that the final signed-off SOP is scheduled to be implemented). Remove “draft” from the header.

7.3 Format and Content of SOPs

7.3.1 Write the SOP using the formatting and styles (e.g. Arial) as shown in the standard SOP template (Appendix A).

7.3.2 Complete the heading and footer information as shown in the SOP Template.

7.3.3 The effective date refers to the date that the approved SOP is to be implemented.

7.3.4 An SOP index should be created to list all of the approved SOPs, separating them into logical categories (Attachment B). The example below separates the SOPs into categories corresponding to the general flow of the Tumour Biobank operations. Combining the abbreviated SOP category with the series number creates the SOP number. The original list of SOPs may contain gaps in the numbering sequence, in order to accommodate new SOPs in logical order.

Standard Operating Procedure Categories and Numbering System

SOP Category	Category (xx).Sub-category (xx).Sop Number (xxx)
General Institutional Requirements of a Biobank	00.000
Administration	01.001
Participant Recruitment and Management	02.001
Records Management and Documentation	03.001
Facilities Management and Operations	04.001
Quality Assurance	05.001
Safety	06.001
Training	07.001
Material Handling and Documentation	08.01.001
Materials Request and Release	09.001

7.3.5 For new SOPs, assign the next consecutive number in the appropriate category. The SOP version number for each original (new) SOP will be e1.0 (English) or f1.0 (French).

7.3.6 Divide the content into sections as shown in the SOP Template (Appendix A).

7.3.7 For revisions to previously issued SOPs, include a summary of and rationale for the revision in Section 10.

7.3.8 Although SOP attachments may be reviewed, revised and approved separately from the SOP, they should be stored with the applicable SOP.

7.3.9 The SOP index may also contain sub-categories if necessary, as shown above for category 08 – Material Handling and Documentation.

7.4 SOP Maintenance

7.4.1 Institute a review process for SOPs.

7.4.2 SOPs should be reviewed regularly (see Appendix B for suggested review schedule). The SOPs should be reviewed sooner if there are changes to regulations, guidelines, research practice, or institutional policies.

7.4.3 Once an SOP is reviewed, complete the SOP Review Record (Appendix C) file copy with CTRNet and regional biobank central office.

7.4.4 If revisions to an SOP are required, follow the review and approval process (See Section 7.1).

7.4.5 If only revisions to an attachment are needed, modifications may be made without revising the SOP. Revise the attachment, update the version date, and file a copy with CTRNet and the regional biobank central office.

7.5 SOP Distribution and Communication

7.5.1 SOPs should be readily available to all tumour biobank personnel and other identified staff users.

7.5.2 Notify all biobank personnel, management members of the biobank, and other identified staff users of any new or revised SOPs, and the rationale for the SOP or SOP changes. Ideally, direct users should be notified immediately of new/revised SOPs.

7.5.3 Provide training on new or revised SOPs. Document training as appropriate to meet regional or institutional requirements.

7.5.4 Retrieve outdated copies of SOPs and attachments and replace with updated versions.

7.5.5 Outdated SOPs, appendices and SOP indices should be archived.

7.6 SOP Storage

7.6.1 The CTRNet and the regional tumour biobank should create and maintain a central SOP file.

7.6.2 Store the following documents in the central SOP files:

- SOP Distribution Records (Appendix D) or electronic audit trail if relevant.
- Final, approved original and revised versions of each SOP.
- One copy of the original and revised versions of each SOP appendix.
- Original, signed SOP Review Records.
- Copies of SOP training records from the collection sites (if maintained)

7.6.3 For electronic SOPs, final SOPs should be posted in a format that cannot be altered (e.g., .pdf format). Ensure that the electronic files are checked regularly and only current SOPs are referenced.

7.7 SOP Style

7.7.1 Describe each operation in a procedure as a separate step. Make instructions explicit enough so that a qualified individual could perform the procedure by following the instructions. Make instructions explicit enough so that the SOP may be used as a training tool, and easily referred to for guidance during routine work.

7.7.2 Use clear, concise, unambiguous instructions so that the user can understand the requirements. Do not use qualifiers and vague terms such as “usually”, “sometimes”, “normally”, “regularly” or “try to”.

7.7.3 Flow charts may be included, as they are an excellent way of communicating the sequential steps of a process. Equipment diagrams and scanned images can also help personnel understand machinery, and are useful aids during hands-on training sessions.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

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

9.0 APPENDICES

9.1 Appendix A – SOP Standard Template
9.2 Appendix B – SOP Index
9.3 Appendix C – SOP Review Record
9.4 Appendix D – SOP Distribution Record

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
1.1.005	09-01-2008	JdSH	Original Document
1.1.005	July 2011	MMA	• Section 8: TCP2 referenced, links updated • Appendix A: Header generalized • Appendix B: revision period changed to 2 year minimum, SOP 8.02.006 added. • Appendix C: SOP review record updated • Appendix E: SOP deviation report - added
1.1.005 e2.0	May 2012	CMG	Grammatical and formatting throughout Definitions removed Revision History moved to bottom Reference links updates Updated SOP references Revised 7.3 – format and content of SOPs Revised appendices Revised section 7 to reflect new SOP numbering system Deleted Appendix E (Deviation Report) – there is no reference to this appendix in this SOP • Deleted 7.3.6 “For revised SOPs, revise the version number (e.g.,. e1.1 or f1.1 for the first revision).” This is already mentioned in 7.1.3.
01.005 e2.0	June 12, 2012	AJS BAS	Section 7.3.4 table: added sub-category to the heading and added the sub-category # to section 8 SOPs in the table. Added line 7.3.9

DRAFT

STANDARD SOP TEMPLATE

CTRNet Standard Operating Procedure TITLE			
SOP Number:		Version:	
Supersedes:		Category:	

Approved By:	CTRNet Management Group	
	Name	DD/MM/YYYY

Formatting should follow the formatting and numbering used in this template (e.g., Arial 12 font for headings, and Arial 10 font for body text). Abbreviations should be written out in full the first time they appear, followed by the abbreviation in brackets. SOPs should be clear, concise and not overly narrative.

1.0 PURPOSE

Provide a brief purpose of the standard operating procedure (SOP).

2.0 SCOPE

A general statement of what is covered by the SOP (what processes the SOP describes).

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

3.1 *Cross-reference (list) all SOPs relevant to this SOP (Italics).*

4.0 ROLES AND RESPONSIBILITIES

Indicate who is responsible for the procedures and list personnel that the SOP applies to.

Tumour Biobank Personnel	**Responsibility/Role**

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)**

6.0 DEFINITIONS

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

7.0 PROCEDURES

Describe the tasks required to implement each activity, breaking them into logical categories. Include any documentation requirements. Start with a short preamble to introduce the section, if appropriate.

7.1 Heading of First Category (Bold, Arial 10 font)
Provide a step-by-step list of tasks/procedures.

Include bullet points for additional information related to a step/task.

- e.g., associated documents

7.1.1 Sub-Sections as required
a. Include alpha points for additional information related to step/task.

7.2 Heading of Second Category (Bold, Arial 10 font)

7.2.1 Sub-sections

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

List the applicable regulations and guidelines the SOP is governed by. Include current Internet link/url where possible.

8.1 FDA CFR
8.2 ICH / GCP
8.3 Tri Council

9.0 APPENDICES

Appendices are usually revised more frequently than an SOP and can be modified without revising the entire SOP.

- List associated attachments (i.e., forms, checklists)
- The attachments are not part of the official SOP document
- Attachments should include a document name, version date, page X of X in the footer

9.1 Appendix A –
9.2

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions

STANDARD OPERATING PROCEDURES INDEX

SOP Number	SOP CATEGORY/ Title	Date Approved	Review scheduled SOPs should be reviewed no less than every 2 years
00	**General Institutional Requirements of a Biobank**		
00.001	Organizational Chart	N/A	
00.002	Job Descriptions	N/A	
01	**Administration**		
01.001	Obtaining Confidentiality Disclosure Agreements	29-May-2012	May 2014
01.004	Handling Participant (Donor) Complaints	29-May-2012	May 2014
01.005	Administration of Standard Operating Procedures	29-May-2012	May 2014
01.006	Job Descriptions, Roles, and Responsibilities		
02	**Participant Recruitment and Management**		
02.001	Participant Recruitment into Tumour Biobank Program	29-May-2012	May 2014
02.002	Developing and Revising Consent Forms	29-May-2012	May 2014
02.003	Requesting Additional Survey Information	29-May-2012	May 2014
02.005	Obtaining Informed Consent	29-May-2012	May 2014
02.006	Withdrawal of Consent	30-May-2012	May 2014
02.007	Notification of Significant and Relevant Findings	30-May-2012	May 2014
03	**Records Management and Documentation**		
03.001	Information Access Control (Privacy and Security)	30-May-2012	May 2014
03.002	Database Back-up Systems (Privacy and Security)	31-May-2012	May 2014
03.003	Data Transmission to CTRNet Catalogue	31-May-2012	May 2014
03.004	Clinical Annotation	31-May-2012	May 2014
03.008	Document Maintenance	31-May-2012	May 2014
04	**Facilities Management and Operations**		
04.001	Physical Security at Facilities	31-May-2012	May 2014
04.004	Emergency Procedure for Freezer and Refrigerator Failure	31-May-2012	May 2014
04.006	Maintenance of Sample Storage Facility and Equipment	31-May-2012	May 2014
05	**Quality Assurance**		
05.001	Assessing Quality of Tissue Specimens	31-May-2012	May 2014
05.002	Assessing Quality of Nucleic Acids	31-May-2012	May 2014
06	**Safety**		
06.002	Handling Hazardous Chemical Waste	31-May-2012	May 2014
06.003	Immunization and Personnel Accident Reports	01-June-2012	June 2014
07	**Training**		
07.001	Education and Training	01-June-2012	June 2014
08	**Material Handling and Documentation**		
08.01	***Material Handling and Documentation - General***		

08.01.001	General - Labeling and Tracking Materials	01-June-2012	June 2014
08.01.002	General - Biohazardous Material Waste Management	01-June-2012	June 2014
08.01.003	General - Inventory Verification	14-June-2012	June 2014
08.02	***Material Handling and Documentation - Blood***		
08.02.001	Blood - Blood Collection	13-June-2012	June 2014
08.02.002	Blood- Blood Processing and Storage	13-June-2012	June 2014
08.02.003	Blood - Blood Derivatives – Extraction of RNA	13-June-2012	June 2014
08.02.004	Blood - Blood Derivatives – Extraction of DNA	13-June-2012	June 2014
08.02.005	Blood - DNA Extraction from Blood	26-June-2012	June 2014
08.03	***Material Handling and Documentation – Solid Tissue***		
08.03.001	Solid Tissue - Tissue Collection and Transportation	26-June-2012	June 2014
08.03.002	Solid Tissue - Tissue Harvesting	26-June-2012	June 2014
08.03.003	Solid Tissue - Snap Freezing of Tissue	28-June-2012	June 2014
08.03.004	Solid Tissue - Freezing of Tissue in Optimal Cutting Temperature	28-June-2012	June 2014
08.03.005	Solid Tissue - Preservation of Tissue – Parrafin Embedding	28-June-2012	June 2014
08.03.006	Solid Tissue - Sectioning of Tissue – Paraffin and OCT Embedded Tissue	28-June-2012	June 2014
08.03.007	Solid Tissue - Haematoxylin & Eosin Staining of Tissue Sections	26-June-2012	June 2014
08.03.008	Solid Tissue- Tissue Derivatives – Extraction of DNA	28-June-2012	June 2014
08.03.009	Solid Tissue - Tissue Derivatives – Extraction of RNA	28-June-2012	June 2014
08.03.010	Solid Tissue - Tissue Micro Arrays from Paraffin Embedded Blocks	28-June-2012	June 2014
08.03.011	Solid Tissue - Sample Retieval	28-June-2012	June 2014
09	**Materials Request and Release**		
09.001	Sample Shipping and Transportation	28-June-2012	June 2014
09.002	Completion of an MTA (Material Transfer Agreement)	28-June-2012	June 2014
09.004	Material Request and Release	28-June-2012	June 2014

SOP REVIEW RECORD

Name of reviewer: _____

Contact email: _____

Review date: _____

SOP Number: _____

SOP Title: _____

Section	Page Number	Comments and description of change

Additional comments:

INSTRUCTIONS: Please read the assigned SOP and review for any needed updates. Type comments and any applied changes into the table above, adding additional rows as needed. Save as "CTRNet SOP review NUMBER_NAME OF SOP, DATE". Use 1 form per SOP. Edit the SOP with TRACK CHANGES. If no updates are needed, please state so in the "additional comments" section. Return all forms and track-changed SOP by email to [insert name of review coordinator and email address]

SOP DISTRIBUTION RECORD

This template can be used at CTRNet, regional Tumour Biobank office (Director or designate) as well as the local collection sites (Principle Investigator) to track distribution / communication of new/revised SOPs. Electronic audit trail should also be attached to this form.

NEW / REVISED SOP (Number.Version)	**EFFECTIVE DATE** (DD/MMM/YY)	**COMMUNICATED TO USERS (Attach supporting documentation)** (DD/MMM/YY)	**COMMUNICATED BY** (Name)	**TRAINING COMPLETED** (DD/MMM/YY)