CTRNet Standard Operating Procedure Administration of Standard Operating Procedures			
SOP Number:	1.1.005	Version	e1.0
Supercedes:		Effective Date	09 Jan 08
Subject:	Administration of Standard Operating Procedures	Category	Administration

Prepared By:		Jean de Sousa-Hitzler		
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
1.1.005	09-01-2008	JdSH	Original Document

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 repositories.

The purpose of having documented SOPs is to:

- Provide written guidelines for aspects of the CTRNet tumour repository program
- Promote quality and consistency in tissue banking and data collection across the CTRNet member repositories
- Ensure compliance with applicable regulations and guidelines
- Facilitate education and training of repository personnel

2.0 SCOPE

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

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 003.001 Education and Training
3. CTRNet SOP: 7.1.001 Training of Tumour Bank Personnel

4.0 ROLES AND RESPONSIBILITY

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

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Consultant	Writing, Revising and updating technical and organizational SOPs	
Lab Technician/Assistant/Clinical personnel	Writing, Revising and updating technical SOPs	
Tumour Bank Manager	Writing, Revising and updating organizational and administrative SOPs	
SOP Review team	Reviewing, Revising and updating technical and organizational SOPs	

5.0 DEFINITIONS

Audit Trail: Documentation that allows reconstruction of the course of events.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

SOP Authorized Signatory: the Director, or designate, of the CTRNet SOP working committee.

CTRNet Generic SOPs: detailed, written instructions to achieve uniformity of the performance of a specific function commonly performed across various sites of CTRNet repositories. Generic SOPs are aimed to ensure compliance to CTRNet policies.

Site Specific SOPs: designed to achieve similar goals as CTRNet generic SOPs but will describe and outline unique procedures done at specific CTRNet member repositories. The SOPs will outline specialized steps in a format easily understood and followed by trained technicians at sites that wish to adopt it at a later date.

6.0 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	

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

1. CTRNet, management at the regional repositories or repository 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.
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.
3. The SOP should follow the standard format (see SOP template, Appendix 1); the word “draft” should be added to the header. For revisions to previous SOPs, the version number must be revised to the next consecutive number (e.g., .001 becomes .002). The first version of an SOP is always .001.
4. Develop/revise associated attachments, as applicable and revise the version date.
5. Update the SOP index (see Attachment 2) as necessary (e.g., for new SOPs added).

7.2 Review and Approval of SOPs

1. Circulate the draft SOP to the applicable reviewers (SOP working committee, management at local repositories, repository personnel, and other identified staff representatives – e.g., SOP users) for comments.
2. Incorporate the comments, revise the draft version date and circulate the revised draft SOP to the repository Director or designate.
3. Review the final draft SOP for accuracy and completeness and for compliance with regulations, guidelines and standard practice.
4. Obtain approval (from a SOP authorized signatory) of the final SOP.

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

1. Write the SOP using the formatting and styles (e.g., Arial and Times New Roman) as shown in the standard SOP template (Appendix 1).
2. Complete the heading and footer information as shown in the SOP Template
3. The effective date refers to the date that the approved SOP is to be implemented.
4. An SOP index should be created to list all of the approved SOPs, separating them into logical categories (Attachment 2). The example below separates the SOPs into categories corresponding to the general flow of the Tumour Bank 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	SOP Number.Version
General Institutional Requirements of a repository	0.1.001
Administration	1.1.001
Participant Recruitment and Management	2.1.001
Records Management and Documentation	3.1.001
Facilities Management/Operation	4.1.001
Quality Assurance Procedures	5.1.001
Safety	6.1.001
Training	7.1.001
Biological Material Handling and Documentation	8.1.001
Material Release	9.1.001
Shipping and Transportation	10.1.001

5. For new SOPs, assign the next consecutive number in the appropriate category. The SOP version number for each original (new) SOP will be .001.
6. For revised SOPs, revise the version number (e.g., .002 for the first revision).
7. Divide the content into sections as shown in the SOP Template (Appendix 1).
8. For revisions to previously issued SOPs, include a summary of and rationale for the revision in Section 7.
9. Although SOP attachments may be reviewed, revised and approved separately from the SOP, they should be stored with the applicable SOP.

7.4 SOP Maintenance

1. Institute a review process for SOPs.
2. SOPs should be reviewed regularly (see Appendix 2 for suggested review schedule). The SOPs should be reviewed sooner if there are changes to regulations, guidelines, research practice, or institutional policies.
3. Once an SOP is reviewed, complete the SOP Review Record (Appendix 3) file copy with CTRNet and regional repository central office.
4. If revisions to an SOP are required, follow the review and approval process outlined in Section 6.2
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 repository central office.

7.5 SOP Distribution and Communication

1. SOPs should be readily available to all tumour repository personnel and other identified staff users.
2. Notify all repository personnel, management members of the repository, 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.
3. Provide training on new or revised SOPs. Document training as appropriate to meet regional or institutional requirements.
4. Retrieve outdated copies of SOPs and attachments and replace with updated versions.
5. Outdated SOPs, appendices and SOP indices should be archived.

7.6 SOP Storage

1. The CTRNet and the regional tumour repository should create and maintain a central SOP file.
2. Store the following documents in the central SOP files:
   - SOP Distribution Records (Appendix 4) 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)

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.

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7.7 SOP Style

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.
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”.
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, 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

Appendix A. Standard SOP Template

CTRNet Standard Operating Procedure Administration of Standard Operating Procedures			
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Supercedes:		Effective Date	09 Jan 08
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Approved By:		Peter Geary	CEO	09 Jan 08
	Signature	Name	Title	ddMmmyy
Approved By:				
	Signature	Name	Title	ddMmmyy

REVISION HISTORY

SOP Number	Author (initials)	Date Issued	Summary of Revisions

Formatting should follow the formatting and numbering used in this template (e.g., Arial font for headings, and Times New Roman 12 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

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

4.0 ROLES AND RESPONSIBILITY

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

5.0 DEFINITIONS

Provide a list of terms used in the document and include their definitions.

6.0 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)

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

1. Provide a step-by-step list of tasks/procedures.
2. Include bullet points for additional information related to a step/task:
   - e.g., associated documents

1.1.1. Sub-Sections as required

7.1 Heading of Second Category

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

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

E.g.:

1. FDA CFR
2. ICH / GCP
3. Tri-Council

9.0 APPENDICES

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

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

APPENDIX 2:

STANDARD OPERATING PROCEDURES INDEX

SOP Number	SOP CATEGORY/ Title	Review scheduled
0	**General Institutional Requirements of a Repository**	
0.101	Organizational Chart	
0.102	Job Descriptions	
1	**Administration**	
1.1.001	Obtaining Confidentiality Disclosure Agreements from TB personnel	2009
1.1.002	Numbering of Policies, Procedures and Documents	
1.1.003	Reviewing and Modifying SOPs	
1.1.004	Handling Participant (Donor) Complaints	
1.1.005	CTRNet Generic: Administration of Standard Operating Procedures	
2	**Participant Recruitment and Management**	
2.1.001	Particpant Recruitment into Tumour Bank Program	**2009**
2.1.002	Developing, adapting and revising consent forms	
2.1.003	Requesting Additional Survey Information	
2.1.004	Withdrawal of consent	
2.1.005	Notification of Significant and Relevant Findings	
2.1.006	CTRNet generic SOP for Obtaining Informed Consent	2008
3	**Records Management and Documentation**	
3.1.001	Information Access control (Privacy and Security)	
3.1.002	Database Back-up Systems (Privacy and Security)	
3.1.003	Data Transmission to CTRNet database	
3.1.004	Clinical Annotation	
3.1.005	Retention of data for unbankable samples	
3.1.006	Making corrections or changes to records	
3.1.007	Discarding confidential records	
3.1.008	CTRNet Generic Procedure for Records and Documentation	2009
3.1.009	User Access to Computerized Records	
3.1.010	User Passwords Maintenance on Computer Systems	
4	**Facilities Management/Operation**	
4.1.001	CTRNet: Physical Security	
4.1.002	Maintaining temperature and environment at TB facility	
4.1.003	Procedure for back-up power at TB facilities	
4.1.004	Emergency Procedure for Refrigerator and freezer failure	
4.1.005	Monitoring procedures for Refrigerators and Cryogenic freezers	
4.1.006	CTRNet Generic SOP for Maintenance of sample storage facility and equipment FDV.doc	
5	**Quality Assurance Procedures**	

5.1.001	Assessing Quality/purity of Tissue specimens (pathology)	2008
5.1.002	Assessing quality of paraffin and frozen tissue sections	2008
5.1.003	Assessing quality/purity of Extracted Nucleic acids	2008
6	**Safety**	
6.1.001	Procedures for handling biohazardous waste	2009
6.1.002	Procedures for handling hazardous chemicals and waste	
6.1.003	Documentation of immunization and personnel accident reports	
7	**Training**	
7.1.001	Training of Tumour Bank Personnel	2009
7.1.002	Training verification and Competence Assessment	
7.1.003	CTRNet Generic Education and Training Procedure	
8	**Biological Materials Handling and Documentation**	
8.1.001	Labelling and tracking materials	
8.1.002	CTRNet Generic Biological Waste Management procedure	
8.1.003	Inventory Verification	2009
8.1.004	Destruction of Human Specimen Material	
2.000	Blood	
8.2.001	Blood collection	2008
8.2.002	Blood Processing	2008
8.2.003	Human Specimen Annontation: Blood	
8.2.004	Creating Derivatives: RNA Extraction from blood samples	2008
8.2.005	Creating Derivatives: DNA Extraction from blood samples	2008
3.000	Solid Tissue	
8.3.001	Tissue Collection and Transportation to Pathology	2008
8.3.002	Tissue Harvesting	2008
8.3.003	Storage of Frozen Tissue: Snap Freezing	2008
8.3.004	Storage of Frozen Tissue: OCT Freezing	2008
8.3.005	Storage of tissue sections : Paraffin Embedded	2008
8.3.006	Sectioning - Paraffin and Frozen Sections	2008
8.3.007	Human Specimen Annontation: Solid Tissue	
8.3.008	H&E staining of sections	2008
8.3.009	Creating Derivatives: DNA Extraction from solid tissue	2008
8.3.010	Creating Derivatives: RNA Extraction from solid tissue	2008
8.3.011	Creating Derivatives: Tissue Micro Arrays from Parafin embedded blocks	2008
8.3.012	Sample Retrieval	2009
9	**Material Release**	
9.1.001	CTRNet Generic Procedure for Material Request and Release	End 2007

9.1.002	CTRNet Generic Procedure for Sample Shipping and Transportation	2008
9.1.001	Pricing and Invoicing	

APPENDIX 3
SOP REVIEW RECORD

To be done Yearly or As Needed.
Send the original of this completed form to the CTRNet and regional repository central office SOP files.
File a copy of this completed form in the local collection site SOP files.

SOP Title: _____

SOP Number/version: _____ **Effective Date:** _____

The above-named SOP has been reviewed. Revisions are **not** required.

Signature: _____ **Title:** _____

Print Name: _____ **Date:** _____
(DDMMMYY)

The above-named SOP has been reviewed. Revisions **are** required.

Signature: _____ **Title:** _____

Print Name: _____ **Date:** _____
(DDMMMYY)

Comments: _____

Appendix B. SOP Index

Appendix C. SOP Review Record (Optional)

Appendix D. SOP DISTRIBUTION RECORD

This template can be used at CTRNet, regional Tumour Repository 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)

Appendix E. SOP Deviation Report

Needs to be added.