CTRNet Standard Operating Procedure Education and Training			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	01-June-2012

1.0 PURPOSE

Adequate knowledge of the biobank program processes, procedures, related regulations and guidelines is essential to safeguarding the interests of the patient, achieving program goals, maintaining program compliance, data and tissue integrity and overall quality assurance at the biobanks that are part of CTRNet. The purpose is to outline processes and areas in which biobank personnel need to be educated and trained in order to carry out their assigned tasks.

2.0 SCOPE

This standard operating procedure (SOP) covers an outline for training and education of personnel at CTRNet member biobanks. Training is designed to inform, educate, and orient new personnel with relevant material vital to performing their duties. The training is also designed to educate, inform, and update existing personnel with evolving requirements and procedural changes if applicable.

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 3 Education and Training*
3.3 *CTRNet Policy: POL 4 Privacy and Security*
3.4 *CTRNet Standard Operating Procedure: SOP 01.005 Administration of Standard Operating Procedures*
3.5 *CTRNet Standard Operating Procedure: SOP 01.006 Job descriptions, Roles and Responsibilities*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all biobank staff, which may include the following roles:

- Director or Principal Investigator
- Clinical Research Coordinator (CRC)/ Tumour Biobank Nurse
- Pathology Assistant (PA)
- Laboratory staff
- Physicians involved with the tumour biobank program (Oncologists, Surgeons, Pathologists, etc.)
- Management, Information Technology and Administrative staff at the biobanks
- Other roles described in *CTRNet SOP 01.006 Job Descriptions, Roles and Responsibilities* or which may evolve with the tumour biobank

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Tumour Biobank Personnel	Responsibility/Role
All employees	Clinical and technical personnel at the tumour biobank have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their respective duties.
Biobank Director, Manager, or Principal Investigator	The Manager/Director of the tumour biobank and the Principal Investigator (PI) is ultimately responsible for facilitating specific staff training, as well as ensuring that he/she has adequately trained staff to carry out the processes of the program.

5.0 MATERIALS, REAGENTS, EQUIPMENT AND FORMS

The materials, reagents, 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)
Canadian Tri-Council Policy: Ethical Conduct for Research Involving Humans	
CTRNet Policies and Procedures	*CTRNet POL 2 Ethics* *CTRNet POL 1 Informed Consent* *CTRNet POL 5 Records and Documentation* *CTRNet SOP 03.008 Document Maintenance*
National Information Protection legislation and official guidelines	Personal Information Protection and Electronic Documents Act (PIPEDA)
Regional Information Protection legislation and official guidelines	
International Guidelines	Declaration of Helsinki as additional reading (See Section 8.0, Ref. 1)

6.0 DEFINITIONS

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

7.0 PROCEDURES

All biobank personnel must be qualified by professional education, training, and experience to perform their duties. The biobank heads should be qualified to assume responsibility for the proper conduct of the program as well as for ensuring that all persons assisting with the program are adequately informed and trained to perform their duties. Aside from appropriate professional and technical qualifications, knowledge of and sensitivity to ethical and regulatory requirements are essential to program compliance and success.

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There are many processes and issues that are common to all biobanks. Personnel at the regional biobanks should receive training in these issues as well as training in issues and processes specific to their particular site

7.1 Core Training Modules

A core module should deal with general ethical considerations that are relevant in tumour biobanking such as:

7.1.1 Ethics

7.1.1.1 Discuss and provide current overview of:

a. Moral issues associated with the use of Human Biological Materials in Research.
b. Participant consent issues.
c. Role of the Research Ethics Board (REB) in the approval of consent and material release process.

7.1.1.2 Provide CTRNet policies POL 2 Ethics, and POL 1 Informed Consent to personnel (or equivalent biobank-specific policies) to read.

7.1.1.3 Provide the Canadian Tri-Council Policy statement: Ethical Conduct for Research Involving Humans, to biobank personnel to read (See Section 8.0, Ref. 8.2).

7.1.1.4 Recommend Declaration of Helsinki as additional reading (See Section 8.0, Ref. 8.1).

7.1.2 Training in Privacy Issues

7.1.2.1 Familiarize personnel with the principles of the federal Personal Information Protection and Electronic Documents Act (PIPEDA) and provincial statues such as the Personal Health Information Protection Act (PHIPA) (or as applicable to the province of operation). Discuss the implications of these privacy guidelines on the relevant aspects of the tumour biobank operation.

7.1.2.2 Provide CTRNet Policy *POL 4 Privacy and Security* to personnel to read.

7.1.3 Training in Best Practices for Record Keeping and Documentation

7.1.3.1 Instruct personnel about optimal documentation and reporting practices to ensure security, integrity, and accuracy of information and data handled by the biobank.

7.1.3.2 Provide CTRNet Policy *POL 5 Records and Documentation,* and *CTRNet SOP 03.008 Document Maintenance* (or equivalent biobank-specific policies) for personnel to read.

7.1.4 Training in CTRNet SOPS

7.1.4.1 Design and present a core-training module to provide personnel with a master list and location of CTRNet generic SOPs (or equivalent biobank-specific policies and SOPs). Advise personnel to read and gain familiarity with the procedures relevant to their job function.

7.2 Site-specific Training

The site-specific training may contain information on:

a. Occupational health and safety with specific details pertinent to the site.
b. Physical security at the site

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c. Relevant technical procedures applicable to personnel and operations at the sites such as derivation of tissue products.
d. Maintaining records, updating inventories and databases, interfacing with CTRNet databases if relevant to personnel at the site.

7.2.1 Design and present site-specific training module to relevant personnel so that they can perform their duties efficiently and ethically.

7.2.2 Provide for them relevant site-specific policies and SOPs to read and assimilate if relevant to their job function.

7.3 Documentation of Training

7.3.1 Document training as needed to meet provincial and institutional requirements (see optional forms in Appendix A: Master SOP and Policy Training Record, and Appendix B: Employee SOP and Policy Training Record)

7.3.2 Update training records in a timely manner

7.4 Assessment of Training

At the end of a training session and on an ongoing basis, encourage personnel to discuss policies and SOPs and ask for clarification if required. These discussions or sessions will provide some indication if the educational material has been "read and understood".

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 – Master SOP and Policy Training Record
9.2 Appendix B – Employee SOP and Policy Training Record

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
AD 002.001	2005	JdSH	
7.1.001 e1.0	2008	JdSH	Revised to make minor formatting changes and reviewed to reflect current practice at the member banks. Updated to new numbering standard.

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7.1.001 e2.0	2011	MMA	Minor revisions: "biobank" used instead of "repository" to make consistent with other CTRNet SOPs. Section 7.1: Added "or equivalent" for required SOPs to be included in training module. References: Updated links and made reference to TCPS2
7.1.001 e2.0	2012	SD	Comments made for name and title to reflect organizational in put rather than a single individual
7.1.001 e2.0	May 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 8 – Updated references • Section 5 and 7.1.8- Deleted "*SOP QA 002 Record Keeping and Documentation"*

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MASTER SOP AND POLICY TRAINING RECORD

Use of the “Master SOP and Policy Training Record ” is recommended.

SOP or Policy Number	SOP or Policy Title	Date of Training	Name of Trainer	Name of Attendee

Retain in SOP files

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EMPLOYEE SOP AND POLICY TRAINING RECORD

Use of the “Employee SOP and Policy Training Record” is recommended.

SOP/POLICY Number	SOP/POLICY Title	Date of Training	Name of Trainer

Retain in employee file

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