CTRNet Standard Operating Procedure Education and Training			
SOP Number:	7.1.001	Version	e1.0
Supersedes:	AD 002.001	Effective Date	09 Jan 08
Subject:	Education and Training	Category	Training

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	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.

1.0 PURPOSE

Adequate knowledge of the tumour repository 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 repositories that are part of CTRNet. The purpose of this Standard Operating Procedure (SOP) is to outline processes and areas in which repository personnel need to be educated and trained in order to carry out their assigned tasks.

2.0 SCOPE

The SOP covers an outline for training and education of personnel at CTRNet member repositories. 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 SOPS OR POLICIES

1. CTRNet Policy: POL 002.001 Ethics
2. CTRNet Policy: POL 003.001 Education and Training
3. CTRNet Policy: POL 004.001 Privacy and Security
4. CTRNet SOP: 1.1.005 Administration of Standard Operating Procedures
5. CTRNet SOP: 0.102 Job descriptions, Roles and Responsibilities

4.0 Roles and RESPONSIBILITY

This SOP applies to:

- Director or Principle Investigator
- Clinical Research Coordinator/ Tumor Repository Nurse
- Pathology Assistant (PA)
- Laboratory staff
- Physicians involved with the tumour repository program (Oncologists, Surgeons, Pathologists, etc.)
- Management, Information Technology and Administrative staff at the repositories.
- Other roles described in SOP 0.102 or may evolve with the tumour bank.

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
All employees	Clinical and technical personnel at the tumour repository have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their respective duties.	
Tumour bank Director or Manager	The Director of the tumour repository or the Principle 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, 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 002 Ethics CTRNet POL 001 Participant Consent CTRNet POL 005 Documentation CTRNet SOP QA 002 Record Keeping and Documentation
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

Compliance: The state of conformity of a regulated party or a product with a legislative or regulatory requirement or a recognized standard.

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.

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

All repository personnel must be qualified by professional education, training and experience to perform their duties. The repository 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.

There are many processes and issues that are common to all repositories. Personnel at the regional repositories 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 tissue banking such as:

i. Ethics

1. Discuss and provide current overview of:
   - Moral issues associated with the use of Human Biological Materials in Research
   - Participant consent issues
   - Role of the Research Ethics Board (REB) in the approval of consent and material release process.
2. Provide CTRNet policies POL 002 Ethics, and POL 001 Participant Consent to personnel to read.
3. Provide the Canadian Tri-Council Policy statement: Ethical Conduct for Research Involving Humans, to repository personnel to read (See Section 8.0, Ref. 2).
4. Recommend Declaration of Helsinki as additional reading (See Section 8.0, Ref. 1)

ii. Training in Privacy Issues

2. 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 bank operation.
3. Provide CTRNet policy POL 004 Privacy and Security to personnel to read.

i. Training in Best Practices for Record Keeping and Documentation

1. Instruct personnel about optimal documentation and reporting practices to ensure security, integrity, and accuracy of information and data handled by the repository.
2. Provide CTRNet policy POL 005 Documentation and CTRNet SOP QA 002 Record Keeping and Documentation for personnel to read.

ii. Training in CTRNet SOPS

Design and present a core training module to provide personnel with master list and location of CTRNet generic SOPs. Advice personnel to read and gain familiarity with the procedures relevant to their job function. This will include procedures on Material Release and Material Handling (CTRNet SOP# 9.1.004)

7.2 Site-specific Training

The site-specific training may contain information on:

- Occupational health and safety with specific details pertinent to the site.
- Physical security at the site
- Relevant technical procedures applicable to personnel and operations at the site s such as derivation of tissue products.
- Maintaining records, updating inventories and databases, interfacing with CTRNet databases if relevant to personnel at the site.

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

1. Document training as needed to meet provincial and institutional requirements (see optional forms in Appendix AMaster SOP and Policy Training Record and Appendix BEmployee SOP and Policy Training Record).
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, 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; Canadian Institute of Health Research; 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. Master SOP and Policy Training Record

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

MASTER SOP/POLICY TRAINING RECORD

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

Retain in SOP files

Appendix B. 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