CTRNet Policy Education and Training			
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Approved By:	CTRNet Management Group (CMG)	08-Feb-2013
	Per: Brent Schacter	08-Feb-2013

1.0 INTRODUCTION

Adequate knowledge of the tumour biobank program processes, 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 members of CTRNet. Personnel must understand the responsibilities of the biobanks as the "custodians" of Human Biological Materials (HBM) for research purposes and be appropriately qualified by education, training and experience to perform his or her task in an efficient, professional and ethical manner.

2.0 DEFINITIONS

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

3.0 PURPOSE

The Canadian Tumour Repository Network (CTRNet) is committed to promoting and educating biobanks to achieve adherence to high ethical standards and practices in the collection and storage of human tissue for research purposes. The purpose of this CTRNet policy is to outline general principles that can be used in most situations to ensure that personnel working at member biobanks are adequately educated and trained to perform their tasks.

4.0 SCOPE

This policy describes recommendations for areas and material that should be the focus of any educational or training process to ensure that ethical and operational standards are maintained at CTRNet tumour biobanks.

5.0 RESPONSIBILITY

This policy applies to CTRNet members and to personnel involved in all aspects of the tumour biobank program. The Principal Investigator (PI) is ultimately responsible for the tumour biobank-specific staff training, as well as ensuring that he/she has adequately-trained staff to carry out the processes of the program. The clinical and technical tumour biobanks personnel have a professional responsibility to obtain and maintain the knowledge and skill sets necessary to perform their relevant duties.

6.0 POLICIES

Learning is a dynamic process. All tumour biobank staff should be qualified by education, training and experience to assume their responsibility for the proper conduct of the program.

6.1 It is optimal that all those involved in the tumour biobank program have necessary skills and knowledge and a clear understanding of the processes and policies that define the running of a compliant, efficient and successful program.

6.2 It is important that the personnel have a clear understanding of their role within the organization and have access to the appropriate level of information to support their decisions and actions.

6.3 Training should be provided for staff who are new and have not previously received such training and for experienced staff who need to keep current with new development, new methods, updated equipment or software and evolving regulatory requirements.

6.4 Training should be designed to meet the needs of the staff working at the collection, storage and central sites if applicable. The scope, detail and content of the training should reflect the particular responsibilities of each site or individual.

6.5 Training should be designed to include general issues such as:

6.5.1 The moral and ethical issues associated with the use of HBMs in research

6.5.2 Regulatory requirements that must be complied with

6.5.3 Best practices for record keeping and reporting

6.5.4 Security regarding issues of privacy and confidentiality

6.5.5 Tissue and Information release (material release)

6.5.6 Material Handling (tissue and information processing and storage)

6.6 Training should be designed to include **site-specific** issues that may include:

6.6.1 Facility security and procedures

6.6.2 Occupational health and safety

6.6.3 Technical procedures and processes relevant to operations at the site (e.g. deriving HBM products such as DNA, RNA, protein and tissue microarrays)

6.6.4 Maintaining records, updating inventories and databases

6.7 Biobanks should consider implementing procedures by which they can assess and evaluate whether or not the personnel have achieved the learning outcomes of the training component.

6.8 Tools used for training such as policies or standard operating procedures (SOPs) should be updated in a timely manner so as to accurately reflect current practice.

6.9 Staff should be mandated to keep current in their area of expertise. This could include attending relevant seminars, conferences, continuing education courses and keeping professional certification updated.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

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

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

7.3 Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations **http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php**.

7.4 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/.

7.5 USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. http://www.fda.gov/oc/gcp/default.htm or
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

7.6 Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. **http://www.hhs.gov/ohrp/policy/ictips.html**

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

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 001.001	Feb 2006	JDSH	Original document
POL 3 e1.2	April 2009	P. Geary	Updated document format. Revised numbering.
POL 3 e2.0	Feb 2013	CMC	• Reviewed and revised by CTRNet Management Committee • Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates