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

1.0 INTRODUCTION

Human biological specimens have been the basis of pathological inquiry for a very long time. However, with the advancement of molecular biology and genetic insights, scientists have greatly increased their use and demand for properly prepared and clinically annotated tissue samples that yield valuable insights into the mechanisms and pathways of human disease.

Research on human tissue samples has not been always formally regulated or extensively harmonized by governing agencies. Existing guidelines for the protection of human subjects in clinical research continue to provide oversight for the use of human biological material (HBM) in basic and translational research in general. These guidelines have been applied to dealing with issues related to collection, study, storage, transfer and disposal of tissue specimens and associated patient data.

In view that HBMs are becoming a valuable and irreplaceable resource and society's interest in the advancement of medical knowledge, this policy is intended to foster a consistent and coherent ethical framework that should govern specimen use.

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 for adherence to high ethical standards and practices in the collection and storage of human tissue and annotating data for research purposes. This CTRNet policy is intended to outline general principles that can be used in most situations to ensure that the interests of the patient are safeguarded.

4.0 SCOPE

This policy applies to major ethical considerations that arise in the conduct of tissue banking and/or research. The issues concern custodianship, risk, confidentiality, consent and quality of research.

5.0 RESPONSIBILITY

This policy applies to CTRNet member biobanks and to personnel involved in all aspects of the tissue biobank program.

6.0 POLICIES

The use of HBM and accompanying data is critical for medical research. The public and program participants should have confidence that biobanks and researchers will use and handle such material according to recognized ethical standards. It is important to ensure that collections of HBMs are used ethically and optimally for the research to benefit health and knowledge. The interests of the participants should always take precedence over the interests of research, science and society.

The following principles in areas requiring ethical consideration should guide the CTRNet biobanks in collecting, maintaining and managing the resource it controls:

6.1 Ethics Review

The following principles should guide the CTRNet member biobanks in the process of obtaining consent.

6.1.1 To ensure that the interests of the patient are safeguarded, processes such as consent, collection, storage and proposed research should be reviewed and approved by an appropriately constituted Research Ethics Board (REB).

6.1.2 The standard of “minimal risk” should be considered in the review process. The physical risks in donating tissue samples for research may be minimal, but the risk that information from research on the sample and annotated data could harm the privacy and confidentiality of the participant should be considered.

6.1.3 Biospecimen and annotation data collection should be conducted under REB approved collection protocols. Typically this will involve obtaining informed consent directly from participants. Participants should be informed and understand what the tissue sample is to be used for. In some circumstances an REB may provide a “waiver of consent” on behalf of the participants.

6.2 Confidentiality

Personal and medical information and research results relating to the participant and tissue sample should always be treated as confidential. The participant should be made aware of the type of personal and medical information that will be used by researchers, and what safeguards will be in place to protect their confidentiality and anonymity.

6.3 Economic Factors

6.3.1 Economic factors may provide motivation for participants to provide tissue samples but this could compromise the quality and safety of the collection. Subjects should not be offered or receive any financial compensation for participation in the program. Participants may be reimbursed for costs involved in participation. Human biological material (HBM) collected from participants should be treated as gifts.

6.3.2 HBMs should not give rise to financial gain. The CTRNet biobanks should not sell (for a profit) samples of HBMs that they have collected. A reasonable payment from users of the biobanks to recover costs of obtaining, managing, maintaining, processing and handling the biobank collection is however acceptable.

6.4 Custodianship of Tissue Data

6.4.1 Custodians should bear responsibility for the samples and data in their collection so that biobanks will be able to safeguard the interests of the participants.

6.4.2 Custodians of the tissue samples should bear responsibility for keeping proper records of all uses that have been made of the materials, whether by themselves or others. If transfer of material occurs, appropriate material transfer procedures should be followed and documented.

6.4.3 Custodians of "Existing Collections" should ensure that they make optimal use of the resource they control and seek the advice of the established REB through periodic (e.g. annual) review.

6.5 Commercialization and Intellectual Property Issues

6.5.1 The development of new drug therapies and diagnostics to a point where they can be made available to universally benefit society is very dependent on commercial involvement. Access by the commercial sector to HBMs within the biobanks should be facilitated if consistent with the goals of the biobanks. However, no one commercial enterprise should be given exclusive rights of access to the collection. Patients should be informed in the consent process, that samples or their products may be used by academic researchers as well as researchers in the commercial sector and that they will not be entitled to a share of the profits that may ensue from research. Disclosure that there is the possibility or intent to commercialize research might help alleviate ethical concerns that participants are not aware of intended uses of their tissue.

6.5.2 Intellectual property (IP) rights arising from research using human samples may be sold or licensed in the same way as other IP rights. Before allowing access to samples by either academic or commercial sector researchers, the biobanks or "custodian" of the HBMs and data should make clear (by contractual agreement) its policies on ownership of IP.

6.6 Genetic Testing

6.6.1 The ability to study samples stored in tumour biobanks and to generate information about genetic disease and susceptibility to disease has raised concerns over risk to participants associated with discrimination and stigmatization of individuals. Privacy of research results should never be breeched, as the consequences for the participant are likely to be social, economic and psychological.

6.6.2 Much genetic information generated as results from research is of unknown or uncertain predictive value. Results should never be disclosed to the patient or added to medical records unless consent is obtained through an REB approved protocol. If consent is sought, then appropriate counselling must be available. During this counselling, participants should be advised of the potential risks and implications of genetic information (e.g. on family members, relationships, employment, and insurance).

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 Meslin, E. and Quaid, K. Ethical issues in the collection, storage, and research use of human biological materials. J Lab Clin Med. 2004;144:229-34

7.8 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

7.9 National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999. http://bioethics.georgetown.edu/nbac/hbm.pdf

7.10 Hakimian, R and Korn, D. Ownership and Use of Tissue Specimens for Research. JAMA. 2004; 292(20):2500-2505. *Ownership and Use of Tissue Specimens for Research* - Acce

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 002.001	Feb 2006	JDSH	Original document
POL 002.002		JDSH	Sections of SOP affected.
POL 2 e1.2	Apr 2009	P. Geary	Updated document format, revised numbering.
POL 2 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