CTRNet Policy Governance			
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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, there has been a significant increase in the 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. These guidelines have been applied to issues related to collection, storage, transfer and disposal of tissue specimens and associated patient data. Of the many institutions now involved in banking of HBMs, few have developed written policies, documents or protocols defining the rights and obligations of the biobanks or the participants.

In that HBMs are becoming a valuable and irreplaceable resource, and society has a growing interest and investment in the advancement of medical knowledge, consistent and coherent governance should encompass biobanking and specimen use.

2.0 DEFINITIONS

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

3.0 PURPOSE

The Canadian Tissue Repository Network (CTRNet) is committed to the highest 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 applied in developing and implementing good governance for biobanks to ensure that the interests of the patient and all other stakeholders are safeguarded.

4.0 SCOPE

This policy applies to major governance considerations that relate to the conduct of research biobanking. The following principles apply to all CTRNet member biobanks. Currently CTRNet founding member biobanks comprise a consortium of six leading provincial tumour biobank programs and these each includes many affiliated biobanks within each province. CTRNet does not encompass all tumour biobanks, but offers a certification program for member/affiliated tumour biobanks that includes a commitment to adopt a more general CTRNet required operating procedure (ROP) on governance.

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

CTRNet member biobanks and their personnel should be aware that appropriate governance principles can reassure biobank participants that the biobank has processes in place to protect their interests in the use of their biospecimens and personal data. The following principles should guide the CTRNet member biobanks for establishing good governance mechanisms.

The way in which the individual biobank puts these principles into operation should be scaled in relation to the biobank's size of operations, and should be adapted so that they are appropriate to the mission and goals of the biobank and are in accordance with institutional policies.

6.1 Declaration of Purpose

To ensure that the biobank will be governed by the overarching principles of transparency and accountability, the biobank will have a clearly defined purpose/mission (i.e., primary focus of research it supports) and operational scope and this will be made publicly available.

6.2 External Governance and Accountability

Compliance with the laws, codes, and agency and institutional requirements that exist in Canada is required. These external governance elements include:

6.2.1 Canadian legislation and regulations governing the collection, use dissemination, retention and destruction of human biospecimens and associated data for research purposes.

6.2.2 Canadian professional codes of conduct where these overlap with stakeholders' activities (e.g., Medical licensing bodies and societies).

6.2.3 Biobanks that provide human biospecimens and associated data for research purposes must undergo ethics review and approval by a research ethics board (REB). Certification and/or accreditation of the biobank by an external body may be beneficial for this review process.

6.2.4 Other requirements from funding agencies/organizations/foundations and host institutions may also be delineated and comprise additional external accountability factors (e.g. annual reporting, creation of advisory boards) that should be incorporated into the internal governance of the biobank.

6.3 Internal Governance and Accountability

An organizational structure should be clearly defined to encompass at a minimum the following roles and elements; leadership, management of operations, and contact and access processes. This organizational structure, including identification of individual(s) who will perform these roles, may be influenced by external stakeholders (such as the institution in the case of large biobanks) and approval will normally be part of ethics review and approval. This structure should be accepted by all those who assume a defined role, should be known to all staff, and also be a matter of public record. The biobank can choose to assign the different roles within the structure to an individual, individuals, or committees and this should be based on factors relating to the nature of the biobank, including its size, sources of funding, stakeholders, and the number of anticipated users of the biobank. This means that for a small biobank all roles might be assumed and performed by one individual who accepts all these roles while for a large biobank some of these roles might be performed by a committee.

6.3.1 This internal governance structure must include components that perform the following roles:

a) Leader/Director/PI Role: This component is responsible overall for biobank staff, daily operations of the biobank partnership activities and funding and reporting or accountability to institutions or agencies. The individual(s) identified in this role also may be nominated to perform the roles of the Operations and/or Access Roles (e.g., for a small/mono-user and moderate-sized/oligo-user biobanks).

b) Operations Management Role: This component establishes and oversees standards for the operations of the biobank, including standard operating procedures (SOPs), quality control (QC), quality assurance (QA), and data protection policies used when handling and storing biospecimens and their derived data, as well as other data from participants. This role will also review performance including participant and biospecimen accrual.

c) Oversight of Access Role: This component oversees the processes that govern research access and utilization of the biospecimens and data in the biobank.

6.3.2 In addition to the required roles listed above, the governance structure may also include other roles, performed by individual(s) with the following additional components:

a) Public/Participant Advisory Role: This role provides advice to the biobank on all aspects of the biobank, with specific emphasis on participant concerns.

b) Ethics Advisory Role: This role provides advice and if required, oversight in the areas of law, ethics and the public's perception of biobanks.

c) Scientific Advisory Role: The role provides advice to the biobank on the scientific plan for the biobank.

6.4 Access to the Biobank

Each CTRNet member biobank is independently governed, funded, operated, and is the principle custodian of its materials. Therefore each biobank needs to be able to determine its own access priorities to take into account the priorities of its local/regional governance, funders and stakeholders. However, each biobank also commits to strive with the Network to make materials nationally or internationally available where possible and feasible after these local priorities have been addressed and to achieve harmonization of standards and operations. The principles and processes relating to access and release that CTRNet biobanks agree to adopt include the following:

All CTRNet Biobanks:

6.4.1. Are accessible through transparent access processes to relevant and independently approved projects that have also passed ethical review.

6.4.2. Provide publicly accessible information on their biobank (such as through the CTRNet registration register).

6.4.3. Provide publically accessible information around how to contact and apply for access.

6.4.4. Provide publically accessible information on priorities for determining access and release.

6.4.5. Entertain and respond with a decision to all reasonable requests for access.

6.4.6. Provide information on their criteria and review processes, as delineated in the relevant CTRNet SOP.

6.4.7. Will have the option, if supplies are adequate, of making samples available to commercially supported projects that meet scientific and ethical criteria, on a full cost-recovery or similar basis.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINE

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

7.2 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/.

7.3 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

7.4 Canadian Federal Personal Information Protection and Electronic Documents Act. http://laws-lois.justice.gc.ca/eng/acts/P-8.6/index.html

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

7.6 UKCCSG Guide to Biological Studies Version 1.0, 2002

7.7 US National Biospecimen Network Blueprint
http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

7.8 Teodorvic, I. et al. Human tissue research: EORTC recommendations on its practical consequences. Eur J Cancer 2003; 39:2256-2263.

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 008 e2.0	Mar 2013	CMC	Original document