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

1.0 INTRODUCTION

The value of the human biological material (HBM) for research purposes is greatly enhanced by accompanying personal or clinical data related to the individual providing the sample. Personnel should treat any information about the individual, however derived, as confidential.

Rules protecting the privacy of personal information collected for research purposes are outlined in national research ethics guidelines. Privacy is also protected by several Canadian statutes such as the federal Personal Information Protection and Electronic Documents Act (PIPEDA) and provincial statutes.

To comply with the guidelines on privacy and confidentiality, participants should be informed about how information about them will be used. Tumour biobanks should have each participant's explicit consent to obtain, store and use information about them. (cf. Policy 1 – Informed Consent) Participants should also be made aware of what safeguards are in place to protect their confidentiality.

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 compliance with national and provincial guidelines and laws safeguarding the privacy and confidentiality of participants that have provided personal and clinical data and tissue samples to the member tumour biobanks. The purpose of this CTRNet Policy is to outline general principles to ensure that the privacy of the patient is safeguarded.

4.0 SCOPE

This policy applies to privacy and confidentiality considerations that arise in the conduct of tumour biobanking and research. The issues concern storage, transmission, retention and sharing of participant information in a manner compliant with legislative and ethical requirements.

5.0 RESPONSIBILITY

This policy applies to CTRNet members and to personnel involved in all aspects of the tumour biobank program that have access to patient information, samples and research results.

6.0 POLICIES

The use of HBMs and accompanying data is critical for medical research. The public and participants should have confidence that biobanks and researchers will use and handle such material with confidentiality. It is important to ensure that sensitive information is used ethically and optimally for the research to benefit health and knowledge. Safeguarding the privacy of the participants should be of primary importance.

The following set of policies or principles should guide the CTRNet biobanks in collecting, maintaining and managing the confidential information it controls:

6.1 Accountability for Personal Information

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

6.1.1 Accountability of CTRNet's member biobanks for compliance to the privacy policy and applicable legislation rests with each member's biobank director or designated official for day-to-day collection and processing of personal information. The name of the designated official, accountable for overseeing compliance to these principles, should be a matter of public record.

6.1.2 As the custodian of personal information in its possession, including information that may be transferred to a third party, the biobank should use contractual means (such as an MTA-Material Transfer Agreement) to ensure a comparable level of protection while the information is being used by the third party.

6.2 Identifying Purposes for the Collection of Personal Information

Personal and linked medical information relating to the participants and tissue samples 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.

6.3 Consent for the collection use and disclosure of Personal Information

6.3.1 Consent is required for the collection of personal information and the subsequent use and disclosure of this information. The biobanks should seek consent for the use or disclosure of the information at the time of HBM collection.

6.3.2 In keeping with the concept of 'informed consent', the biobanks should make an effort to ensure that the participants are advised of the overall purposes for which their information will be used. Participants should be confident that biobanks will follow the guidance of a Research Ethics Board (REB) for reviewing and approving access to their material.

6.3.3 Information should not be used for purposes that have not been specifically identified in the consent process without seeking the guidance of the REB of record.

6.4 Limiting Collection

The member biobanks will not collect personal information indiscriminately. Both the amount and the type of information will be limited to that which is necessary for the purposes identified by the collecting biobank in the consent process.

6.5 Limiting Use, Disclosure, and Retention of Personal Information

6.5.1 Personal information should not be used or disclosed for purposes other than those for which it was collected.

6.5.2 The biobank should control the release of information to researchers by evaluating each request for scientific merit and compliance with approved ethical standards. Researchers using the tumour biobank can only use HBMs or disclose information in accordance with the terms and conditions outlined in a Material Transfer Agreement (MTA).

6.5.3 The local tumour biobank should develop guidelines and implement procedures (approved by an REB) with respect to the retention of personal information:

a) For cases of withheld consent, all case related tissue and data held (electronically or on paper) by the local biobank should be removed or destroyed.

b) For cases of revoked consent, all case related tissue and data should be limited or destroyed. Guidance of the involved REB should be used in the management of case related tissue and data accrued, that cannot be destroyed as it may already be engaged within a research protocol. In some cases, such material may be used as anonymous donor/tissue without information about clinical characteristics and with REB approval.

6.6 Accuracy of Personal Information

To minimize the possibility that inappropriate or insufficient information may be used to make decisions or conclusions about the research undertaken, personal information and data should be accurate, complete and up-to-date.

6.7 Ensuring safeguards for Personal Information and HBMs

6.7.1 The security safeguards should protect HBMs and personal information against loss or theft as well as unauthorized access, disclosure, copying, use or modification. CTRNet biobanks should protect personal information and HBMs regardless of the format in which it is stored.

6.7.2 Security safeguards appropriate to the sensitivity of the personal and clinical information should protect this information.

6.7.3 Methods of ensuring security of HBMs and associated information should include the following methods:

a) Physical measures such as locking biobank filing cabinets, freezers, fridges and restricting access to offices and laboratories.

b) Organizational measures, such as limiting access on a 'need-to-know' basis.

c) Technological measures, such as using passwords, firewalls, and encryption.

d) Encoding procedures such as de-identification or de-personalization of source data.

e) Routine back-up of data and information stored electronically.

6.8 Openness about Personal Information Polices and Practices

6.8.1 CTRNet biobanks should be open about their policies and practices with respect to management of personal information. Participants should be able to acquire information about policies and practices without unreasonable effort and this information should be made available in a form that is generally understandable.

6.8.2 CTRNet biobanks should make information about policies and practices available in a variety of ways. This may include brochures available at its place of business or at promotional events and online access to policies, forms and selected educational material.

6.9 Individual Access to Own Personal Information

6.9.1 Personal information includes data that has been collected (including lifestyle and clinical data) but not data created by research.

6.9.2 Exceptions to individual access should be controlled by the REB and may be warranted if the information contains references to other individuals, is prohibitively costly to provide, is not traceable or cannot be disclosed for legal, security or commercial proprietary reasons.

6.9.3 If valuable medical information becomes available from research on biobank samples, the decision to contact the patients or their families to offer benefits of that research should be guided by the REB of record and best clinical practice.

6.10 Complaints

Biobanks will put procedures into place to receive and respond to complaints or inquiries about its policies and practices relating to the handling of personal information. The procedure should be easily accessible and simple to use.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

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 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

7.4 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

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

7.6 Ontario's Personal Health Information Protection Act http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

7.7 Alberta's Freedom of Information Protection of Privacy Act http://www.oipc.ab.ca

7.8 Alberta's Health Information Act.
http://www.assembly.ab.ca/HIAReview/Health_Information_Act.pdf

7.9 British Columbia's Freedom of Information Protection Act.
http://www.oipc.bc.ca/legislation/FOI-ACT%20(2004).pdf

7.10 Manitoba's Freedom of Information and Protection of Privacy Act (FIPPA) and Personal Health Information Act (PHIA) http://www.ombudsman.mb.ca/access.htm

7.11 Quebec's Act respecting access to documents held by public bodies and the protection of personal information.
http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/A_2_1/A2_1_A.html

7.12 American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility. 2003. J. Clin. Oncol. 21(12):2397-2406.

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 004.004	Feb 2006	JDSH	Original document
POL 4 e1.1	Apr 2009	P. Geary	Updated format. Revised numbering.
POL 4 e1.2	Jan 2012	BAS	Reviewed and revised by CTRNet Management Committee
POL 4 e2.0	Nov 2012	A. Spakowski	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates