CTRNet Policy Records and Documentation			
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Approved By:	CTRNet Management Group (CMG)	20-Dec-2013
	Per: Brent Schacter	20-Dec-2013

1.0 INTRODUCTION

Recent developments in molecular biology and genomics have essentially enhanced the value of clinically annotated human tumour tissue in translational research and drug discovery. Adherence to best practices in the generation and maintenance of complete and accurate documentation is important in ensuring the value and utility of resources within the tumour biobank. Intellectual property rights (IPR) can only be protected adequately if all records and documents are thorough, accurate and contemporaneous.

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 for research purposes. The generation of clear, accurate, comprehensive and retrievable records and documents are vital to the biobanks compliance and success. The purpose of this CTRNet policy is to outline general principles that can be used by biobanks to insure that records and documents are maintained with common essential standards.

4.0 SCOPE

This policy applies to all records and documents that have to be generated and maintained as part of the operation of the tumour biobank. The policy covers written notebooks, original paper records, true copies such as photocopies, microfiche or microfilm as well as electronic records and documents (e.g. CD, DVD, USB, etc.).

5.0 RESPONSIBILITY

As custodians of Human Biological Materials (HBMs) and associated information, biobanks have a responsibility to maintain complete and auditable records. This policy applies to CTRNet member

biobanks and to personnel involved in generating, maintaining and managing records and documents within the tumour biobank program.

6.0 POLICIES

The use of HBMs and accompanying data is critical for medical research. Clear, accurate and complete records are essential to any research program. As custodians of samples of HBMs, biobanks are responsible for keeping proper records. The following principles should guide the CTRNet biobanks in maintaining compliant records and documents.

6.1 Collecting and managing information and data

6.1.1 Confidentiality of personal information as well as data associated with tissue and biological samples is essential. All personal information must be encoded as early as possible after collection.

6.1.2 Data records should be monitored to ensure completeness and accuracy.

6.1.3 Custodians of HBMs are responsible for keeping proper records of all uses that have been made of the material, whether by themselves or by others.

6.1.4 Custodians of HBMs should ensure that all uses have appropriate Research Ethics Board approval, and keep copies of such approvals for easy reference.

6.1.5 When linked encoded samples are provided to a third party, the custodian is responsible for safe keeping of the code enabling samples to be linked to individual donors.

6.2 Retaining information and data

6.2.1 Retention of accurately recorded and retrievable information, data and results are essential for the running of a tumour biobank and should be retained as long as the biobank Principal Investigator deems them to be pertinent. Prior to destruction of any information or data the governing Research Ethics Board must be consulted.

6.2.2 Researchers (who are leaving an establishment) that generated data and who wish to retain anonymised data/copies of data for future use must get specific permission to do so from both the biobank and from the appropriate Research Ethics Board (REB). Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the consent and contract with that researcher. A material transfer agreement (MTA) should govern this transaction.

6.3 Retention of Data in the Case of Withheld or Revoked Consent

Publication of data imposes a requirement that researchers and the local biobanks retain source data or records.

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

6.3.2 For cases of revoked consent, all case related information and data should be limited or destroyed. Guidance of the REB of records 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 the clinical characteristics and with REB approval.

6.4 Notebooks and Electronic Records

6.4.1 All raw data or personal and clinical information should be recorded and retained in laboratory notebooks or in an electronic database dedicated to that purpose.

6.4.2 Machine print-outs, consent forms, questionnaires, chart recording, autoradiographs, forms, letters, etc. which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross-indexed with the main record.

6.4.3 Notebook and electronic records should be entered as soon as possible after the data is collected or generated. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should be clearly identified and dated.

6.4.4 There should be processes in place for quality assurance of data collected and recorded electronically.

6.4.5 Where feasible, internal annotated digitized data/images should be recorded and retained in a “raw” or original format as well. This is especially relevant where data/images undergoing digitization are subsequently enhanced. If possible, both the original and enhanced forms should be stored.

6.4.6 Electronic records should be backed-up regularly; duplicate copies should be held on disc in a secure but readily accessible archive.

6.5 Personnel and Users Access to Information and Records

Access to data should be given to users on a ‘need to know’ basis. Users should be granted access to specific data records that they need in order to perform their duties. This access should be removed when the activity is completed.

6.6 Transmission of Information and Data

Information from incoming sources (such as regional collection sites and CTRNet member biobanks) should be transmitted in a secure manner.

6.7 Physical Storage of Information and Data

6.7.1 Data and records should be stored securely and with appropriate contingency plans.

6.7.2 Data and records should be stored in a manner to permit retrospective audit if needed.

6.7.3 Records and back-up discs should be stored to maximize protection from factors such as flooding, fire or theft.

7.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

7.1 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/.

7.2 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

7.3 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org

7.4 Medical Research Council, Ethics Series. Good Research Practice http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Researchpractice/principles_guidelines/index.htm

7.5 Good Laboratory Practice for nonclinical lab studies (CFR21-Chapter1 Part 58 Subpart J (58.185, 58.190 and 58.195)

8.0 APPENDICES

None

9.0 REVISION HISTORY

Policy Number	Date Effective	Author	Summary of Revisions
POL 005.001	Feb 2006	JDSH	Original document
POL 5 e1.1	Apr 2009	P. Geary	Updated format. Revised numbering.
POL 5 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
POL 5 e2.1	Dec 2013	RB	• Revised section 6.2.1-Addition of text.