| CTRNet Policy<br>Informed Consent | | | |
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| Approved By: | CTRNet Management Group (CMG) | 08-Feb-2013 |
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## 1.0 INTRODUCTION

The use of human tissue for the purpose of medical research has gained importance in the advancement of knowledge, testing of new therapies and diagnostics, and elucidation of disease. Tumour tissue removed in the course of surgical treatment or expressly for research purposes or excess human material left over from diagnostic testing is a valuable research tool. However, the use of human tissue in research raises ethical issues based on the moral status of human tissue. The access to and use of data associated with, or derived from, human tissue is also an ethical issue.

Research Ethics Boards (REBs) provide a mechanism to allow ethical issues to be considered on behalf of potential participants and for appropriate information to be presented to potential participants to allow them to provide informed and voluntary consent. Informed and voluntary consent is a fundamental requirement for ethical research involving human subjects. Consent can be obtained from the participant before the use in medical research, of human materials surplus to clinical requirements to obtain direct consent on behalf of participants. The consent process requires sensitivity to the dignity, cultural notion and physical integrity of the individual participant in the tumour biobank program.

## 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 purpose of this CTRNet policy is to outline general principles for best practice that should be used by CTRNet member biobanks, in obtaining voluntary and informed consent from the tumour biobank participants.

## 4.0 SCOPE

This policy applies to participant consent issues. It outlines best practices for the process of obtaining informed and voluntary consent from the participants, for the acquisition of participant clinical data and tissue material surplus to clinical requirements, specifically for use in medical research.

## 5.0 RESPONSIBILITY

This policy applies to CTRNet member biobanks and especially to personnel involved in:

- Developing and adapting participant consent forms
- Providing information to the patient about the tumour biobank program
- Obtaining consent from the potential participant

## 6.0 POLICIES

CTRNet member biobank personnel should be aware that there are personal sensitivities associated with the donation of tissue and be cognizant of this issue before approaching potential participants. Voluntary and informed consent is a key mechanism for protecting the rights of the participants. Consent encompasses the process that starts with initial contact and carries through to the end of the involvement of the participants in the project.

It should be noted that the Tri-Council Policy Statement on ethical conduct for research involving humans (7.4) addresses the issue of informed consent comprehensively. This policy is intended to provide a summary relevant to biobanking but does not supersede in any way the Tri-Council Policy Statement.

### 6.1 Obtaining Consent for Specimen Collection

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

6.1.1 The collection and use of human tissue for research should be undertaken with voluntary and informed consent of competent participants. Consent should also be obtained to collect or access personal and clinical information from medical records.

6.1.2 Consent should be obtained voluntarily, without manipulation, influence or coercion. It must also be made clear that a participant can revoke consent at any time, and that a decision not to participate in the program will in no way compromise the standards of medical care the patient will receive.

6.1.3 Under certain circumstances, an REB may provide a waiver of consent.

6.1.4 In the case of minors or incompetent participants, consent should be obtained from an authorized third party (Legally Acceptable Representative).

6.1.5 Consent should be obtained in writing.

6.1.6 When seeking consent, information for participants, legally acceptable representatives, impartial witnesses or an intermediary should be presented in a clear form that can be easily understood. Lack of proficiency in the operating language should not disqualify participants. In this case, an intermediary competent in the language should translate the relevant information and the participant should acknowledge in his or her language an understanding of the project, the extent of his or her participation, the risks involved and freely give consent.

6.1.7 Participants should be aware of financial consideration. It should be made clear that they will not receive any compensation for their participation in the program. If any new tests, discoveries or products with potential commercial value result from research on their tissue, they will not share in financial benefits.

6.1.8 Issues of privacy and confidentiality should be discussed with the participant. If relevant, the participant should be informed about identifying information attached to specific tissue and its potential traceability. How this could affect privacy should also be covered. Safeguards to protect the individual's privacy and confidentiality should be outlined.

6.1.9 The written informed consent form and any other written information to be provided to the participants should have the written approval/favourable opinion of an appropriate REB. Any revisions to the informed consent form or the written information should receive the REB approval/favourable opinion in advance of use.

6.1.10 During the consent process participants should also be provided with information about:

a) The purpose of the program

b) The type and expected amount of the tissue to be taken, if applicable

c) The manner in which the tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of storage

d) The potential uses for the tissue as known (objectives of research)

e) The potential users of the biobank (academic and commercial users)

f) Potential risks and benefits if any to the participant

g) As known, who will access tissue, personal clinical and research information, what information will be obtained and how the patient's privacy and confidentiality will be protected

h) How surplus material will be disposed of, should it be no longer needed

**6.2 Consent for Existing Collections**

The following principles should guide the CTRNet member biobanks in consent issues relating to existing collections.

 

6.2.1 There are historical collections held within CTRNet tumour biobanks. Consent for these collections may have been obtained for a single research project, for teaching, or for use as clinical assay controls. Alternatively, the consent may not meet the current standards for informed consent, or the parameters of consent may not have been adequately documented, or consent may not have been obtained.

6.2.2 Since obtaining consent retrospectively is often impossible or impractical, the ultimate use of these collections should be guided by the REB. Therefore, biobanks must ensure that the status of such collection is reviewed periodically (e.g. annually) by the REB, and REB approval to continue to maintain them must be obtained. Consideration should be given to their value, the parameters and conditions under which they were collected, and the issues and difficulty involved in obtaining re-consent for such samples.

6.2.3 Any new research projects that involve access to such collection should be reviewed by an REB, as is the case for use of all biobank materials. The researchers seeking access to these tissues should be made aware, if historical collections are provided, about the potential deviations, if any (or lack of information), from the currently established Standard Operating Procedures (SOPs). This information should be disclosed to researchers if the conditions of accrual and storage are documented.

## 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 Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. 2005; 165(1):97-100.

 

7.9 Fonds de la recherche en sante du Quebec : Rapport final Groupe-conseil sur l'encadrement des banques de donnees et des banques de material biologique a des fins de recherche en sante. Depose au conseil d'adminstration du FRSQ le 8 decembre, 2006.

http://www.frsq.gouv.qc.ca/fr/ethique/pdfs_ethique/Sommaire_groupe_conseil_francais.pdf

## 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 001.002 | | JDSH | Updated SOPs affected |
| POL 1 e1.2 | Apr 2009 | P. Geary | Updated document format, revised numbering. |
| POL 1 e2.0 | Feb 2013 | CMC | • Revised content<br>• Grammatical and formatting throughout<br>• Definitions removed<br>• Revision History moved to bottom<br>• Reference links updates |