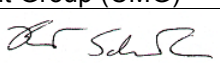
CTRNet Standard Operating Procedure Withdrawal of Consent			
SOP Number:	02.006	Version:	e2.0
Supersedes:	2.1.003 e1.0	Category:	Participant Recruitment and Management

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter 	30-May-2012

1.0 PURPOSE

Participation in the tumour biobank program is voluntary. As part of the informed consent process, participants are informed that they can withdraw consent at any time and for any reason. For example, if patients have social, philosophical, religious or family concerns they may decide to withdraw consent.

2.0 SCOPE

The scope of this standard operating procedure (SOP) is to outline the general procedures that should be undertaken to deal with this situation so as to uphold the rights of the participant when consent for the participant is withdrawn.

These steps may be adopted as is, or modified by specific CTRNet member biobanks at their collection sites to allow for the incorporation of site-specific details, conditions and Research Ethics Board (REB) requirements provided none of the changes alter the spirit of the SOP or result in a reduction of the protection of the rights of the participant.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 1 Informed Consent.*
3.2 *CTRNet Policy: POL 2 Ethics*
3.3 *CTRNet Policy: POL 4 Privacy and Security*
3.4 *CTRNet Standard Operating Procedure: SOP 02.005 Obtaining Informed Consent*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank personnel and clinical staff at the collection centres that are involved in receiving the request for withdrawal of consent and to those involved in taking follow-up action. This may include the following personnel:

Tumour Biobank Personnel	**Responsibility/Role**
Clinical Research Coordinator (CRC)/Clinical Research Nurse, Tumour Biobank Manager, Oncology Physicians (Surgeons/Oncologists) at the Cancer	Receiving request for withdrawal of Consent Forwards the request to the Biobank Director

Centre/Hospital or their designates	
Tumour Biobank Manager or Director	Issues a directive to deem the samples un-bankable Ensures that the materials and data have been processed The tumour biobank director may at their discretion delegate the authority to act on their behalf within this SOP
Tumour Biobank Technician/Technologist/Bioinformatics or Database Personnel	Take follow-up action after consent is withdrawn to delete patient information (paper and electronic records), and discard samples as required.

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	**Materials and Equipment (Site Specific)**
Withdraw consent request (written or oral)	
Confirmation documentation that sample has been removed from records	
Inventory system and database	
Unused samples from participant revoking consent	

6.0 DEFINITIONS

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

7.0 PROCEDURES

The participant may withdraw consent at any time. Personnel at the tumour biobank should take appropriate steps to respect the will of the participant and ensure that the participant is able to withdraw without consequence.

7.1 Request to Withdraw Consent

7.1.1 A donor or an authorized third party may withdraw consent at anytime.

7.1.2 The request to withdraw consent may be made verbally or in writing and addressed to responsible personnel at the collection sites or tumour biobank.

7.1.3 Document the reason if voluntarily provided by the donor or authorized third party.

7.1.4 Document withdrawal of consent.

7.2 Follow-up Action After Receiving the Request for Withdrawal

7.2.1 After receiving the request for withdrawal of consent the personnel should re-assure the participant that there would be no consequences or negative impact on their normal course of treatment and care.

7.2.2 Notify the biobank director or assigned delegate that the participant's consent has been withdrawn and the samples are deemed un-bankable.

7.2.3 Upon receipt of a withdrawal instruction, the biobank director issues an instruction to withdraw to the relevant biobank personnel involved in both biospecimen and data aspects, instructing them to implement and comply with Section 7.3 of this policy.

7.2.4 When required as per institutional policy documentation of withdrawal may be provided to the REB and/or a certificate of destruction may be provided to the participant.

7.3 Follow-up Action After Receiving the "Instruction to Withdraw"

There are two scenarios to consider; the biospecimen and/or data have been collected by the biobank but a) not distributed for research or, b) all or a portion has been distributed for research.

7.3.1 Upon receipt of an "Instruction to Withdraw" the tumour biobank staff will determine whether scenario a) or b) applies.

7.3.2 Under both scenarios, ensure that unused tissue and other unprocessed biological samples from the participant that remain in the biobank are destroyed.

7.3.3 Under both scenarios, delete all personal identifying information. In scenario a) all electronic and physical records are deleted or destroyed. In scenario b) in accordance with institutional policy anonymized records and samples may be maintained. REBs may require that the original paper copy of the consent be maintained.

7.3.4 Do not collect any additional information about the individual from any source.

7.3.5 According to institutional policy samples such as embedded tissue blocks may need to be returned to the pathology department.

7.3.6 If required, store a log of all purged and discarded samples from withdrawn consent patients.

7.3.7 Should a back up of the inventory database/informatics system ever be restored, the director should ensure that identifying records are not restored.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

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

8.2 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/

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

8.4 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

8.5 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

8.6 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
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.006 e1.0	2008	JdSH	Original document
2.1.006 e1.0	May 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Used the term withdraw instead of revoke throughout • Section 1: minor wording changes, deleted 2nd paragraph • Section 2: 1st paragraph deleted and replaced with second paragraph from section 1(purpose). • Section 7.2: added #4 • Section 7.3: added an opening paragraph, changed the wording on all the points to reflect the new opening paragraph (with 2 scenarios)