CTRNet Standard Operating Procedure Withdrawal of Consent			
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Subject:	Withdrawal of Consent	Category	Participant Recruitment and Management

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
2.1.006	2008	JdSH	1st Release.

1.0 PURPOSE

Participation in the tumour bank program is totally voluntary. Patients go through the informed consent process and as part of the process, participants are informed that they can withdraw consent at any time. If at any time, patients have social, philosophical, religious or family concerns they may decide to withdraw consent.

The purpose 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to deal with this situation so as to uphold the rights of the participant when consent for the participant is withdrawn.

2.0 SCOPE

The SOP covers what should be done once the request for withdrawal has been received by the repository.

These steps may be adopted as is, or modified by specific CTRNet member repositories at their collection sites to allow for the incorporation of site-specific details, conditions and REB requirements provided none of the changes alter the

spirit of the SOP or result in a reduction the protection of the rights of the participant.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 001.001 Informed Consent.
2. CTRNet Policy: POL 002.001 Ethics
3. CTRNet Policy: POL 004.001 Privacy and Security
4. CTRNet SOP: 2.1.005 Obtaining Informed Consent

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank 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 Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Clinical Research Coordinator (CRC)/Repository Nurse/Tumor Bank Manager, Oncology Physicians (Surgeons/Oncologists) at the Cancer Centre/Hospital or their designates	Receiving request for withdrawal of Consent Forwards the request to the bank Director	
Tumor Bank manager/Director	Issues a directive to deem the samples un-bankable Ensures that the materials and data have been processed under	The Bank Director may at their discretion delegate the authority to act on their behalf within this SOP
Tumor Bank Technician/Bioinformatics or Database Personnel	Take follow-up action after consent is withdrawn.	

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)
Revoked consent request (written or oral)	
Confirmation that sample has been removed from records	
Inventory system and database	
Unused samples from participant revoking consent	

6.0 DEFINITIONS

Informed and Voluntary Consent: A process by which a subject voluntarily confirms his or her willingness to participate in the tumour repository program, after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Participant: An individual (patient or healthy volunteer, if applicable) who participates in the Tumour Repository Program. The terms patient, participant, subject and potential donor may be used interchangeably.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term ‘bank’ and ‘repository’ is used interchangeably.

7.0 PROCEDURES

Consent may be withdrawn revoked by the participant at anytime. Personnel at the tumour bank should take appropriate steps to respect the will of the participant and ensure that the participant is able to withdraw without reprisal.

7.1 Request to revoke consent

1. A donor or an authorized third part may revoke consent at anytime.

2. The request to revoke consent may be made verbally or in writing and addressed to responsible personnel at the collection sites or tumour bank (as indicated in the consent form).
3. Attempt to confirm withdrawal from the participant or authorized representative and try to identify the reason for revoking consent.
4. Document withdrawal of consent.

7.2 Follow-up action after receiving the request for withdrawal.

1. After receiving the request for withdrawal of consent the personnel should re-assure the participant that there will be no reprisal or negative impact on their normal course of treatment and care. Participants should also be advised that a certificate of destruction can be provided if requested.

2. Notify the bank Director or assigned delegate that the participant's consent has been withdrawn and the samples are deemed un-bankable.

3. Upon receipt of a withdrawal instruction, the bank director issues a instruction to withdraw to the bank Tumour Bank Technician and Bioinformatics instructing them to implement and comply with Section 3 of this policy

7.3 Follow-up action after receiving the "Instruction to Withdraw".

1. Upon receipt of an "Instruction to withdraw" the bank staff will ensure that unused tissue and other unprocessed biological samples from the participant are destroyed.

2. Permanently break any link between personal identifying information and the anonymized records in the inventory system or Bioinformatics database.

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

4. Return all embedded blocks obtained from pathology back to the pathology department.

5. Processed "products" derived from the tissue and blood samples (such as repository embedded blocks, sections, smears and molecular products) should not be destroyed.

6. Only anonymized data for the processed products may be used for future research after consent has been revoked.

7. If the tissue sample was released for a research study before consent was withdrawn, do not take any action to recover the sample.

8. Store a log of all purged and discarded samples from revoked consent patients.

9. Should a back-up of the inventory database/informatics system ever be restored, then the director should ensure that identifying records stored on the

discarded samples log (that are relevant to the samples) are deleted from the records again.

10. Shred any hard copies of associated identifying information.

11. The director should certify that identifying links have been broken, that unused and unprocessed biological material has been destroyed by signing a confirmation form documenting this action.

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
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/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html
4. Tri-Council Policy Statement; 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, August 1998. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
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 www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
6. Office for Protection from Research Risks, US Department of Health and Human Services, Tips on Informed Consent. http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm
7. First Generation Guidelines for NCI-Supported Biorepositories. Federal Register, Vol: 71, No. 82, April 2006.

9.0 APPENDICES

None

