CTRNet Standard Operating Procedure Retention of Data for un-bankable Samples			
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Subject:	Retention of Data for un-bankable Samples	Category	Records Management and Documentation

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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

The purpose of this procedure is to ensure that when the samples have been deemed un-bankable, the participant rights and privacy are protected.

A sample is deemed un-bankable when a consent has been has not been obtained within the prescribed period or consent has been deemed invalid (ex. Withdrawn, or invalidated by the REB).

Under these conditions all identifying data and associated clinical data must be deleted from the tumour bank inventory or informatics system.

2.0 SCOPE

The SOP covers what should be done to participant data once the sample is considered un-bankable for whatever reason under two scenarios:

(1) The materials has not been processed into derivative products

(2) The material has been processed into derivative products and/or has been released to researchers.

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 reduced regard of the informed consent process or enforcement of privacy protection .

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: 2.1.006 Obtaining Informed Consent
5. CTRNet SOP: 2.1.005 Withdrawal of Informed Consent
6. CTRNet SOP: 2.1.001 Participant Recruitment into Tumour Bank Program

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel at the collection centers and tumor repositories that are involved in taking follow-up action once a sample is deemed un-bankable.

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumor Bank manager/Director	Determines when a sample is deemed un-bankable and initiates follow-up action.	
Tumor Bank Technician/Bioinformatics or Database Personnel	Take follow-up action after sample is deemed un-bankable. Deletes or anonymizes data.	

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)	
Consent forms not completed at time of expired consent period	
Inventory system and database	

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.

Expired Consent Period: The maximum time period allowed for a sample to be stored without consent obtained is 6 months. This period applies to retrospective consent only, and begins when the initial sample of the patient is first accessioned and ends when consent is obtained in writing. If consent is not obtained within this 6 month period, the sample is un-bankable and should be purged from the system. The time period is at the discretion of the local REB.

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

Banking of samples for which there is no voluntary consent is against national and international guidelines. Samples obtained without proper consent must not be used in research studies and must be purged from the system (See CTRNet Policy 001.001 Informed Consent).

7.1 Deleting information for revoked consent: when tissue has not been processed

1. Delete all electronic data and destroy (shred) hard copies of **Personal Identifying Data.** This may include consent forms, questionnaires, and copies of clinical

documents or label as “no consent available” if the software does not allow deletions.

2. Delete **Anonymous Data**, which can be released to researchers, including diagnosis, gender, age at diagnosis, race, de-identified clinical documents and questionnaire.

7.2 Deleting information for revoked consent when materials have been released

Where tissue has been processed or for tissues and products released to researchers (revoked consent samples only)

1. Delete all electronic data and destroy (shred) hard copies of **Personal Identifying Data.** This may include consent forms, questionnaires, and copies of clinical documents. Alternatively, label as “no consent available” if the software does not allow deletions.

2. Retain **Anonymous Data**, which has been released to researchers, including diagnosis, gender, age at diagnosis, race, de-identified clinical documents and questionnaire.

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

