CTRNet Standard Operating Procedure Participant Recruitment into a Tumour Bank Program			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
6.1.002	2008	JdSH	1st Release.

1.0 PURPOSE

The value of the collection is proportional to the number, diversity and quality of the tissue samples banked in the program. Voluntary participation of patients will influence the success of the banking program. To promote participation, tumour bank personnel and associated clinical professionals at the participating institutions must ensure that appropriate patients are identified, approached and ethically recruited to participate in the banking initiative.

2.0 SCOPE

The SOP covers the procedures for identifying and recruiting patients in the tumor repository program. Consent may be obtained either prospectively or retrospectively. This SOP covers steps that should be followed when obtaining consent prospectively or retrospectively. 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 requirements.

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 recruiting patients and the acquisition of informed and voluntary consent. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Clinical Research Coordinator (CRC)/Repository Nurse/OR Nurse	Obtaining and Documenting Informed Consent and identifying patients for recruitment	
Oncology Physicians (Surgeons/Oncologists) at the Cancer Centre/Hospital or their designates, Principle Investigators	Patient recruitment	

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)**
Informed Consent Form	
Participant Recruitment Log	

6.0 DEFINITIONS

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a subject's identity.

Expired Consent Period: The maximum time period allowed for a sample to be stored without consent obtained is 6 months (or as deemed appropriate by the local REB). 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 unbankable.

Consent Pending: Patients who have been identified for the Tumour Bank Program, who have had the informed consent process initiated, have been given the consent form and have been invited to participate in the program.

Consented Patient: A patient who has consented to participate in the program and consent documentation is completed (Consent form completed).

Inclusion Criteria: The criteria that study subjects must meet to be eligible for participation in the program.

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.

Prospective Consent: Prospective consent is obtained prior to the patient undergoing surgery or biopsy to remove the tumour for usual patient care. It is envisaged that consent could be obtained prior to surgery in the surgeon's office or in the pre-operative area.

Recruitment: The processes and activities used to identify and recruit patients for the Tumour Bank Program, from base patient population through to enrollment into the program.

Recruitment Log: The form/Spreadsheet used to record patient pre-screening and screening activities/data, if and when (date) consent was received. If consent was not received, record reason on the log.

Retrospective Consent: Retrospective consent is obtained after the patient has undergone surgery or biopsy to remove the tumour for usual patient care. It is envisaged that consent could be obtained post-surgery while the patient is recovering from surgery in the hospital, at the first follow-up visit to the cancer centre or physician's office, or at the first treatment visit after diagnosis.

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

Informed consent is obtained either before or after tumour resection occurs. The attending surgeon or their delegate (nurse, coordinator etc.) will conduct/supervise prospective consent. If prospective consent has not been obtained they will follow-up with trying to obtain retrospective consent. If consent has not been obtained by the expired consent period (see definitions) then the sample will be regarded as unbankable and treated accordingly.

At no time should participation in the tumour bank program mean that the patient's diagnosis, or the Pathology Department's ability to interpret test results is in any way compromised. The tissue block should never be depleted. If at any time the Pathology department needs access to patient material, they should be able to access it.

Consent may be obtained in a prospective or retrospective manner (see Definitions). In both situations, the following procedures apply:

7.1 Inclusion Criteria

To be suitable for participation in the Tumour Bank Program the patient must meet the following criteria:

1. Must be able to give informed consent as outlined in the Informed Consent SOP 2.1.005.

2. Must be greater than 18 years of age.

3. If less than 18 years of age (paediatric patients), informed consent must be obtained from legally acceptable representatives (parents or legal guardians). See SOP 2.1.005 Section 7.3.1.

4. Typically, patients scheduled to undergo surgery should be recruited for the program. Healthy individuals scheduled to undergo surgery for procedures such as breast reduction may be approached (with appropriate Informed Consent Forms) to provide tissue for normal controls in research studies.

5. Exclude patients that have a very small sample size and there is concern that banking the sample will adversely compromise routine diagnosis or the future needs of the pathology department. However, these patients may be included if clinical tissue blocks can be accessed for the purpose of generating Tissue Microarrays.

7.2 Prospective Consent

If a patient meeting the inclusion criteria is identified by the surgeon or designate then Prospective Consent should be obtained prior to resection of the tumour using the latest version of the Research Ethics Board Informed Consent form. The person obtaining informed consent should be qualified by training to do so, and knowledgeable about the tumour repository program.

1. If the patient agrees to participate in the program:
    - Review the Consent form and ensure that is properly completed,
    - Provide the participant or legal representative with a copy of the signed form,
    - File original signed form securely,
    - (Optional) File a third copy of the form with the patient medical record at the site if local practice requires such action,
    - Record that consent was obtained in the computerized database or inventory system and in the Recruitment Log (see Appendix 1); and
    - Schedule or perform blood collection from the participant.

2. If the patient refuses to participate in the Tumour Bank Program
    - Document refusal in the Recruitment Log; and
    - Communicate refusal to relevant Tumour Bank or clinical personnel.

7.3 Retrospective Consent

It will not always be possible to obtain prospective consent. In these cases tumours from the potential participant may be processed to archive-readiness but follow-up with the patient to obtain consent within the expiry consent period. Be sure to inform them that a sample of leftover tissue has been identified as suitable for banking and is being held in the pathology department.

1. If the patient agrees to participate in the program:
    - Review the Consent form and ensure that is properly completed,
    - Provide the participant or legal representative with a copy of the signed form,
    - File original signed form securely,

- (Optional) File a third copy of the form with the patient medical record at the site if local practice requires such action,
- Record that consent was obtained in the computerized database or inventory system and in the Recruitment Log (see Appendix 1); and
- Schedule or perform blood collection from the participant.

2. If the patient refuses to participate in the Tumour Bank Program within the expiry consent period or the expiry consent period has elapsed and consent still has not been received:

- Document refusal in the Recruitment Log if relevant,
- Document that the expiry consent period has lapsed,
- Communicate refusal or lapsed consent period to relevant Tumour Bank or clinical personnel; and
- Purge the sample from bank database system as per operating procedure for un-bankable samples.

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. 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
4. 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
5. 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
6. Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. Arch Intern Med. 2005; 165(1):97-100.
7. Patient Recruitment to Tumour Bank. OCRN Draft SOP: TB301.001 Feb. 2004.

9.0 APPENDICES

Appendix 1: Prospective or Retrospective Participant Recruitment Log

Prospective or Retrospective Participant Recruitment Log

		PRE-CONSENT		CONSENT SIGNED			
Participant Initials	**Hospital Medical No. or sample identification code**	**Consent Information session conducted?**					
		Check [X]	Comments	Yes	No	Date Of Decision	If no, reason