

Participant Recruitment into a Tumour Biobank Program

CTRNet Standard Operating Procedure Participant Recruitment into a Tumour Biobank Program			
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Approved By:	CTRNet Management Group (CMG)		01-May-2012
	Per: Brent Schacter		28-May-2012

1.0 PURPOSE

The cost and value of a tumour biobank is proportional to several factors including the participant accrual rate and the number, diversity and quality of the biospecimens banked in the program. Voluntary participation by patients is a central factor in the success of the biobanking program and also provides patients with opportunities to support research. To promote participation, tumour biobank personnel and associated and collaborating clinical professionals at participating institutions should work to ensure that appropriate patients are recruited.

2.0 SCOPE

This standard operating procedure (SOP) covers the overall processes for identifying, approaching and recruiting patients for the purpose of obtaining consent to participate in a tumour biobank program. The SOP is relevant to tumour biobank programs that collect biospecimens that are derived from standard medical procedures and that are not required for clinical diagnostic pathology requirements. Please refer to *CTRNet SOP 02.005 Obtaining Informed Consent* for details of the procedure for obtaining informed consent. These processes 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 requirements.

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 centers that are involved in recruiting patients and the acquisition of informed and voluntary consent. This may include the following personnel:

Tumour Biobank Personnel	Responsibility/Role
Tumour Biobank Director or Coordinator	Developing an appropriate recruitment plan in conjunction with Oncology physicians (surgeons/oncologists) at the

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	cancer centre/hospital or their designate
Clinical Research Coordinator (CRC)/Biobank Nurse/Appropriately trained consenting personnel	Obtaining and documenting informed consent and identifying patients for 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

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

7.0 PROCEDURES

Informed consent is obtained either before or after a medical procedure (e.g. surgery) that yields a potentially available biospecimen and can occur, through either pre or post-procedure Research Ethics Board (REB) approved consent protocols.

Patients may be invited to participate in a research study and donate biospecimens where this involves undergoing procedures specifically conducted to obtain a research biospecimen. In some cases this procedure involves minimal risk (e.g. phlebotomy or buccal swab) and inclusion in the consent form of permission to obtain a blood sample is routine in many tumour biobank programs. However, all other instances that may involve other levels of risk (e.g. obtaining an additional biopsy core during a standard core biopsy procedure that would not have otherwise been taken for diagnosis) fall outside the scope of this SOP and require consultation and approval from an REB for the specific research protocol. Often this increased level of risk needs to be weighed against the value of a specific research question.

7.1 Inclusion Criteria

To be suitable for participation in a Tumour Biobank Program that collects unused biospecimens after a medical procedure and diagnosis, the participant must meet the following general criteria:

7.1.1 As a general rule, must be able to give informed consent as outlined in the *Informed Consent SOP 02.005 – Obtaining Informed Consent* and as detailed in the *Tri-Council Policy on Ethics*.

7.1.2 Must be scheduled to undergo a medical procedure such as surgery that yields a biospecimen as part of their cancer treatment. Healthy or at risk individuals scheduled to undergo procedures other than cancer surgery (such as breast reduction) may participate (e.g. to donate tissues for normal controls) and support cancer research.

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7.2 Other Factors

The determination of availability and appropriateness of a biospecimen or portion thereof for the tumour biobank program should be made by an appropriate clinical professional (usually a pathologist) who should ideally be independent from the tumour biobank program. This determination must be made at the time of potential harvesting from a fresh specimen after a medical procedure and also at the time of potential harvesting from an archival pathology block at any time in the future.

7.3 Phases of Consent Process

The process of obtaining consent by a tumour biobank can be usefully considered as involving three phases or steps:

- 7.3.1 Referral of potential patient (to secure permission to contact). As a research entity the tumour biobank program is not able to identify appropriate participants and is dependent on either relevant health professionals (typically a surgeon or their designate) introducing the program and making a referral (or self referral by a knowledgeable patient). This may often occur during the office visit, at the same time as the clinical diagnosis is established and the decision to proceed to surgery is reached. The introduction of the tumour biobank program can be brief and establishes the permission of the patient to be contacted by the tumour biobank program to discuss further. This introduction may also provide an opportunity to the patient to consider a positive action as part of reacting to the challenge of the diagnosis.
- 7.3.2 Preliminary interview (to ascertain patient interest in the biobank and preference for the format of provision of full information). This step may occur in person or by telephone and can be used to describe the tumour biobank program in general terms, and most importantly to establish the preference of the patient for how to learn more about what is involved in participation (i.e. time and place to meet to discuss consent or medium to receive more information such as by email or mail).
- 7.3.3 Informed Consent (interaction face to face or by phone to discuss in detail what is involved and to document the decision to decline or to provide informed consent by a signed consent form). The details of this step are covered in *CTRNet SOP 02.005 - Obtaining Informed Consent*.

In practice these steps are often merged (e.g. referral and preliminary interview may be merged and conducted at the same time by a physician and informed consent obtained subsequently by the biobank, or all three steps accomplished by a physician). However consideration of the process as a series of steps can be useful in designing deployment of pre or post procedure protocols in specific locations and situations. For example, the mechanism to obtain referrals is often instituted through establishing dedicated collaboration and participation with specific surgeons. Alternatively this mechanism may be expanded to involve the clinic staff to act as designates of the surgeons or oncologists to offer a clinic or unit or centre wide invitation to patients to choose to provide permission to be contacted to consider participation in specified research.

7.4 Pre and Post Procedure Consent Protocols

There are advantages and disadvantages for both the patient and the tumour biobank program to consider around pre-procedure and post-procedure consent protocols. Many tumour biobank

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programs operate both protocols. In either case the local REB must approve the details of the consent protocol.

7.4.1 Pre-procedure consent protocol. A significant number of patients prefer this option. For many tumour biobank programs, such as those led by surgical investigators, it is more efficient and provides an opportunity to secure consent to obtain blood samples before and during procedures and to deploy specialized biospecimen handling protocols with patient consent. Disadvantages include the sometimes short pre-procedure consent period that can preclude consideration by the patient (e.g. patients requiring emergency surgery), high levels of stress experienced by some patients in the pre-procedure period, and the inefficiency for both patient and tumour biobank around taking time to discuss consent when the procedure that follows may not yield an appropriate biospecimen.

7.4.2 Post-procedure consent protocol. A significant number of patients prefer this option. For many tumour biobank programs, such as those led by pathologist investigators, it is more efficient and provides an opportunity to identify potential biospecimens before initiating the process of consent. Disadvantages include the need to deploy mechanisms to secure patient referral to consider consent and to track consent status and actions through the post-procedure consent period.

During the post-procedure consent period a biospecimen that has been collected may be held in temporary storage as an identifiable specimen before consent has been obtained. The identifiable biospecimen is held in an agreed storage location and no research may be conducted until the consent status is known or the period has expired and the appropriate actions have been taken (see Section 7.5 below).

The length of the consent period is defined in consultation with the local REB, and usually lasts until the completion of diagnosis, which may vary for different sites and disease entities, but is typically 3 months to 1 year. During the consent period the consent status (patient consented, patient declined, or no patient decision) of the biospecimen must be determined by the bank, and the appropriate action taken in response to each status category (see below) before the biospecimen is transferred to the custody of the biobank (i.e. accrued) and/or research is conducted on it.

7.5 Actions after expiry of the post procedure consent period.

If a patient meeting the inclusion criteria is referred to the tumour biobank program a post-procedure consent protocol may be followed that culminates in the Informed Consent step using an REB approved version of the Informed Consent Form and as detailed in *CTRNet SOP: 02.005 Obtaining Informed Consent*. The following limitations apply:

7.5.1 The consent status must be determined during the relevant Post-procedure Consent Period.

7.5.2 The consent status will be either patient consented, patient declined, or no patient decision known. An example of this last category is that an interest in being contacted to consider consent was provided by a referral process but a decision was not received before the end of the post-procedure consent period expires.

7.5.3 The appropriate action is taken in response to each consent status category and this should be determined in consultation with the local REB. Typically this action is accrual or destruction. Where the patient's decisions are unknown, anonymization and use of the sample may be approved by the REB.

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- 7.5.4 If the patient is approached as part of a pre-procedure consent protocol and declines to participate in the Tumour Biobank Program:
- Purge all patient's information from the Recruitment Log; and
 - Communicate the decline decision to relevant Tumour Biobank or clinical personnel so that data that may have been collected before the procedure are purged.
- 7.5.5 If the biospecimen is collected as part of a post-procedure consent protocol, and the patient declines to participate in the Tumour Biobank Program within the consent period:
- Purge all patient's information from the Recruitment Log; and
 - Communicate the decline decision to relevant Tumour Biobank or clinical personnel so that data and biospecimens that have been collected are purged.
- 7.5.6 If the biospecimen is collected as part of a post-procedure consent protocol, and the consent period has elapsed and patient decision is not known, a possible action is to anonymize the biospecimen and relevant data (or may be to purge as above) as determined in consultation with the local REB. Anonymization should occur as follows:
- Remove all patient identifying information from the Recruitment Log,
 - Document that the expiry consent period has lapsed,
 - Communicate a patient decision unknown status to relevant Tumour Biobank or clinical personnel so that data and biospecimens that have been collected are anonymized.

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 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
- 8.6 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.
- 8.7 Patient Recruitment to Tumour Bank. OCRN Draft SOP: TB301.001 Feb. 2004.

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- 8.8 Perun, H., Orr, M., Dimitriadis, F. Guide to the Ontario Personal Health Information Protection Act. 2Irwin Law Inc., 2005; p.650.
- 8.9 Hewitt R, Watson PH, Dhir R, Aamodt R, Thomas G, Mercola D, Grizzle WE, Morente MM Timing of consent for the research use of surgically removed tissue: is postoperative consenting acceptable? Cancer. 2009 Jan 1;115(1):4-9.

9.0 APPENDICES

- 9.1 Appendix A – Participant Recruitment Log

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.001 e1.0	Aug 2008	JDSH	Initial release
2.1.001 e1.0	July 2011- Feb 2012	CTRNet Managem ent Group	<ul style="list-style-type: none"> -Grammatical and formatting errors throughout -Added #5 to “Reference to other CTRNet SOPs or Policies” -Information was changed to indicate that all information must be purged from tumour bank records regarding any patient who has refused consent -In reference section: TCP2 referenced and links updated. Added an additional reference (#8) -Appendix 1: removed section of CDAs- this text is irrelevant to the SOP -Appendix 2: Removed-redundant information, all details are found in the reference section -Appendix A: Removed-irrelevant to the SOP
			<ul style="list-style-type: none"> -Revision of description of processes leading to the informed consent process. -Removed details of informed consent process that are dealt with in another SOP. -Changed -technician to technician/technologist; repository to biobank; lab to laboratory - Deleted "Site specific personnel and contact info "column from section 4 -Definitions removed -Changed the approved section -SOP revisions moved to bottom

PARTICIPANT RECRUITMENT LOG

		PRE-CONSENT		CONSENT SIGNED	
Participant Initials	Hospital Medical No. or sample identification code	Consent Information Session Conducted?			
		Check [X]	Comments	Yes	Date Of Decision

Patients who have refused participation, or patients for whom the allowable period of consent has lapsed, must have all information removed from this log.