CTRNet Standard Operating Procedure Requesting Additional Survey Information			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	29-May-2012

1.0 PURPOSE

Participants consent to donate tissue to the tumour biobank (that is surplus to the needs of the Pathology Department) and allow access to their clinical records for future research. The specifics of future research are often not known at the time of consent. Research is shifting towards molecular profiling and the ability to correlate this with longitudinal clinical data, demographic data, lifestyle factors, environmental and occupational exposure, patient medical history and clinical outcomes. Often, such information has not been collected at the time of specimen banking. Should it be deemed valuable to obtain this information, there should be procedures in place for this.

2.0 SCOPE

This standard operating procedure (SOP) covers the procedures that should be in place within the biobank to request additional information from the participant or to ethically obtain this from participant medical records if possible.

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 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*
3.5 *CTRNet Standard Operating Procedure: SOP 02.002 Developing and Revising Consent Forms*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank personnel, clinical and research staff at the collection centres that are involved in requesting additional survey information. This may include the following personnel:

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank Manager, Director, or Principal Investigator	Determining that additional information would be of value and arranging to obtain it.
Research Ethics Board (REB)	Reviewing and Approving any requests that may be made to collect or access additional information.

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)
Documented Informed Consent Form	
Current ethical guidelines	
Request for additional information	

6.0 DEFINITIONS

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

7.0 PROCEDURES

Biobank should strive to collect and store relevant clinical data associated with a specimen to maximize the use of biospecimens for current, future and longitudinal studies. In practice, given finite resources and different priorities between biobanks, the extent of this data may vary for different types or sets of biospecimens.

7.1 Maintenance of Identifying and Contact Information

7.1.1 Maintain (only within the biobank) the ability to store identifying information and contact information for specimens as permitted under law and by patient consent to enable specimen use for longitudinal studies or outcome research.

7.1.2 Ensure that patient privacy is guarded and this information does not reach individuals not authorized to access it.

7.2 Procedures to Request Additional Information

7.2.1 Establish local written procedures to facilitate the submission of a request for outcome data, additional clinical data or lifestyle and medical history.

7.2.2 Determine if this information can be accessed from patient records or if participant contact is required.

7.2.3 Contact the participant only if there is no alternative way to derive the information. The right to re-contact should be addressed in the original consent form (See *CTRNet SOP 02.002 Developing and Revising Consent Forms*).

7.2.4 The biobanks should have procedures to facilitate follow-up with the participants if needed.

7.2.5 Only have dedicated personnel that are specially trained submit this request or contact participants.

7.2.6 Document clear rationale for collecting additional information and specify the value it will bring to the research.

7.2.7 All requests for additional survey information must be approved by the Research Ethics Board (REB) on a case-by-case basis.

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

8.7 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

8.8 Hoeyer K., Olofsson BO., Mjorndal T., Lynoe N. The ethics of research using biobanks: reason to question the importance attributed to informed consent. 2005; 165(1):97-100.

8.9 General Requirements and Documentation for Informed Consent (Code of Federal Regulations, Title 45, Part 46.116-46.117).

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.003 e1.0	Aug 2008	JdSh	Initial release
2.1.002 e1.0	Feb 2012	CMG	• Grammatical and formatting updates throughout. • Section 1: minor edits • Section 7.0: Opening paragraph revised • Section 7.2: #3, Added “The right to re-contact should be addressed in the original consent form (See CTRNet SOP Developing and Revising consent forms)” • Reference links updated • Definitions removed • Updated SOP references • Revision History moved to bottom