CTRNet Standard Operating Procedure Requesting Additional Survey Information			
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Subject:	Requesting Additional Survey Information	Category	Participant Recruitment and Management

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
1.1.001 e1.0		JdSh	Initial release

1.0 PURPOSE

Participants consent to donate tissue (surplus to the needs of the pathology department to the tumour repository) 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 adds enormous value to the research. 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 to do so.

2.0 SCOPE

This SOP covers the procedures that should be in place within the repository 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 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
5. CTRNET SOP # 2.1.002: Developing and Revising Consent Forms

4.0 ROLES AND RESPONSIBILITY

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

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank Manager or Director, Principal Investigator	Determining that additional information would be of value and arranging to obtain it.	
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

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

Consent Form: A consent form is a written document that explains the tumour bank program to the participants. If they agree to participate this document is signed by the participants and must contain information/statements to ensure that subjects are fully informed about 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.

Research Ethics Board (REB): An independent body (a review board or a committee, institutional, regional, national or supranational) constituted of medical and scientific professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the research project, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research program participants.

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

Repositories should strive to collect and store all relevant clinical data associated with a specimen to maximize the use of biospecimens for current, future and longitudinal studies.

7.1. Maintenance of identifying and contact information

1. Maintain (only within the bank) 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.

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

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

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

3. Contact the participant only if there is no alternative way to derive the information.

4. The repositories should have procedures to facilitate follow-up with the participants if needed.

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

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

7. All requests for additional survey information must be approved by the REB on a case-by-case basis.

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

APPENDICES

None

