CTRNet Standard Operating Procedure Requesting Additional Survey Information			
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Subject:	Developing and Revising Consent Forms	Category	Participant Recruitment and Management

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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
2.1.002 e1.0	09-01-2008	JdSh	Initial release

1.0 PURPOSE

Obtaining voluntary consent of participants who have been informed about all the relevant aspects of the program is important for the ethical conduct of the tumour repository program. Participants consent to donate tissue (surplus to the needs of the pathology department to the tumor repository) and allow access to their clinical records for future research. They acknowledge that they understand all aspects of the program and accept associated risks if any. The consent form is an important document in the tissue banking process. It should be developed and revised to comply with current international guidelines, local laws and have Research Ethics Board (REB) approval.

2.0 SCOPE

The SOP covers the procedures for developing and revising consent forms. The SOP covers basic elements of the consent form, preferred legal and cultural language that should be used, REB approval considerations and procedures for developing, reviewing and revising a consent form.

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, clinical and research staff at the collection centres that are involved in developing and revising consent forms. This may include the following personnel:

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank Manager or Director, Principal Investigator	Developing, adapting and revising Consent Forms. Keeping current with ethical guidelines	
REB	Reviewing and approving Consent Forms and keeping current with ethical guidelines	

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 Template	
Current ethical guidelines	

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.

Impartial Witness: A person, who is independent of the tumour repository program, who cannot be unfairly influenced by people involved with the research, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

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.

Legally Acceptable Representative: An individual or judicial or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the tumour repository program.

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.

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

The primary purpose of the Informed Consent Form is to provide written confirmation that informed consent was obtained. It may also serve as a reference for discussion points that should be covered during the consent process. Research Ethics Board (REB) approved information attached to the Informed Consent Form also serves as an ongoing reference for participants.

7.1 Basic Elements of the Informed Consent Form Guidelines

The consent form should contain:

1. Objectives of the tumour repository program. A statement that the specimens will be used in. A blanket explanation of the overall purposes of the research on the specimens. and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject Discuss the risks of participation in the program. Cover risks associated with giving blood which may include bruising, bleeding and infection of the site. Include risks associated with making information from health records available to the tumour repository but specify measures that will be taken to protect privacy and confidentiality.

3. A description of any benefits to the participant or to others which may reasonably be expected from the potential research. Outline that there are no direct benefits to participating in the program but that the new knowledge generated from the research may potentially lead to the development of new tests and therapies for cancer. Individual data if generated will not be made

available to the patient except for in the rare case when the clinical usefulness of the data becomes medically significant.

4. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. Provide assurance that confidentiality of data and identity will be protected.

5. An explanation of whom to contact (such as a patient representative) for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event that the participant wishes to express a concern or complaint.

6. Specification that the patient will not receive any compensation for participation in the program. The patient will also have no share in any revenue generated from any tests, therapies or discoveries generated from research on the tissue or data.

7. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of treatment to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of medical care to which the subject is otherwise entitled to.

8. Include direction and contact information indicating who the participant can contact if they wish to revoke consent. Describe what will take place should consent be withdrawn.

9. A description how the tissue sample, blood and data will be handled, stored and released to researchers.

10. A clear statement informing the patients what participation in the tumour bank will mean for them.

11. An indication of the possibility that the patient could be contacted for additional information at a later date. Contact will be done at the discretion of the REB.

7.2 Revisions to the Consent Form

The person revising the informed consent form should be qualified by training to do so, and knowledgeable about the current ethical guidelines and laws. Revisions should be initiated when:

1. Safety reports or complaints mandate change.

2. International, national, local or institutional ethical and safety guidelines or regulations change.

3. Local or provincial regulations mandate the inclusion of specific elements not in the template or form currently in use.

4. There are amendments to the tumour bank program.

5. The REB recommends change.

6. Local and institutional identifiers need to be inserted.

7.3 Legal and Cultural Language to be used in the consent form

1. Use language that will easily understandable to the participant or the representative.

2. Do not use exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights.

3. Do not use language which releases or appears to release the tumour bank, the investigator, the research sponsor, the institution or its agents from liability for negligence.

4. Tailor consent forms to address the situation in which the consent is being obtained (retrospective or prospective consent).

5. Tailor consent forms to address the demographic population of the participants (paediatric versus adult).

6. Tailor consent forms to address the need for legally acceptable representative or impartial witness if relevant.

7. Use language that respects the culture, traditions and knowledge base of the cultural group being approached to participate in the repository program.

8. Prepare the consent forms in both official languages (English and French).

7.4 REB Approval of Consent Forms

1. Do not use any version of a consent form unless it has been reviewed and received approval from the REB.

2. Whenever it is necessary to revise the consent forms (see section 7.2) have the REB approve revisions.

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).

9.0 APPENDICES

1. Consent Form Template

APPENDIX 1.

CTRNet Consent Form templates when developed.