CTRNet Standard Operating Procedure Obtaining Informed Consent			
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REVISION HISTORY

SOP Number	Author (initials)	Date Issued	Summary of Revisions
PC 101.001	JdSH	2005	CTRNet Generic SOP for Obtaining Informed Consent
2.1.005 e1.0	JdSH	2008	Minor formatting changes and reviewed to reflect current practice at the member banks

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 their leftover tissue (after scheduled surgical treatment) and/or biological material to the tumor repository, allow access to their clinical records for future research, acknowledge that they accept associated risks if any and understand all aspects of the program. Consent is given on the basis that governance of the use of their samples includes the review by an independent Research Ethics Board for each application to use their samples and associated data. The purpose of this Standard Operating Procedure (SOP) is to outline the general steps in obtaining free and informed consent from a participant in a manner compliant with the Canadian Tumour Repository Network (CTRNet) policy on Informed Consent (POL 001.001).

2.0 SCOPE

The SOP covers the procedures for obtaining and documenting initial informed and voluntary consent from a participant in the tumor repository program. It lists in step-by-

step format, the appropriate tasks and procedures that must be followed when obtaining consent. 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

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel and clinical staff at the collection centres that are involved in 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 Technical Staff in Laboratory	Obtaining and Documenting Informed Consent	
Oncology Physicians (Surgeons/Oncologists) at the Cancer Centre/Hospital or their designates	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 with information sheets	

6.0 DEFINITIONS

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

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 an individual voluntarily confirms his or her willingness to participate in the tumour repository program, after having been provided relevant information about the program and about the implications of their decision to participate. Informed consent is documented by means of a written, signed, and dated consent form.

Legally Acceptable Representative: An individual, judicial or other body authorized under applicable law to consent, on behalf of a prospective individual, to the person'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 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.

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 must contain relevant information. 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.

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

7.1 General Informed Consent Guidelines

1 Prior to starting the consent process with a patient, review the CTRNet Policy POL 001.001 Informed Consent. This will provide a basis for ethical considerations that should govern the process.
2 Keep in mind that the rights, safety and well-being of research participants are the most important consideration and should prevail over the interests of the goals of the repository, science and society.

7.2 Obtaining written informed consent

The person obtaining informed consent should be qualified by training to do so, and be knowledgeable about the tumour repository program.

1. After receiving information from the surgeon's/oncologists office about a potential participant, confirm that the most recent version of the REB approved Informed Consent Form is available.

2. Take 2 copies of the Informed Consent Form along to the consent meeting.

3. For the purpose of the consent discussion, meet the participant in a space that offers a quiet and private environment.

4. Having another person (patient's family member or friend) at the consent meeting is acceptable and may help the patient relax, provide support, and facilitate the participant's information retention.

5. Initiate rapport with the patient and assess whether or not, the patient is competent to consent to participate in the tumour repository program. Be sensitive to the possibility that recent diagnosis of a serious illness may be especially stressful and the patient may be in a state of reduced comprehension. The validity of consent obtained under these conditions is questionable.

6. Using the Informed Consent Form as a guide, give the patient information (in clear language) about the following:

    - Objectives of the tumour repository program
    - Confidentiality issues. Reinforce that the discussion is confidential. Provide assurance that confidentiality of data and identity will be protected.
    - Outline procedures the patient will have to undergo.
    - Describe how the tissue sample, blood, other biological material, and data will be handled and stored.
    - Discuss the risks of participation in the program. Mention risks associated with giving blood may include bruising, bleeding and infection of the site. Cover 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.
    - 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 established. In this case, the REB may approve patient contact.
    - Specify 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.
    - Clarify that participation is voluntary. The decision to refuse participation or withdraw from the program, will not affect the standard of care the patient will receive.

7. Allow the participant adequate time to read and assimilate the Informed Consent Form. This may include reviewing the Informed Consent Form at home. Ask the patient questions to assess their comprehension of the material reviewed. Encourage them to ask questions in return and answer the questions as honestly as possible. Provide contact information for the tumour repository so that the patient can obtain additional clarification or ask further questions.

8. If the patient agrees to participate in the tumour repository program, request that the patient sign and date two copies of the Consent Form.

9. The individual obtaining the consent should sign and date two copies of the Consent Form.

10. Provide one copy of the completed Consent Form (along with attached REB approved information) to the participant and retain the other copy for the tumour repository program records.

7.3 Alternate situations for obtaining informed consent

7.3.1 Consent using Legally Acceptable Representative

If after assessing the patient's competence the patient is judged incapable of providing consent, the consent of a Legally Acceptable Representative (see Definitions) can be obtained. Follow the procedures described in Section 6.2 above, but instead obtain the signature of the Legally Acceptable Representative. Indicate on both copies of the Consent Form that the printed name, signature, and date were obtained from the Legally Accepted Representative. Some banks, after consultation with their REB, may decide not to obtain consent by this method.

Situations where samples are collected from paediatric patients (minors) consent from a parent or legal guardian is needed. For teenage patients where level of comprehension and maturity is assessed to be high the patient may sign and parents or guardians may witness the signature. However, these cases may be reviewed in a case by case system by the REB. Each governing institution may have a consent policy and procedure to follow for this situation. Special paediatric consent is usually required for this case. In some collection centres a special ethics review and paediatric review is necessary.

7.3.2 Obtaining Retrospective Consent

From time to time consents will need to be signed in a retrospective manner. This will require a potential participant to give permission for tumor banking after the tumor specimen has been removed from the body and is being temporarily stored in the tumor bank facility. Until the potential participant signs the ICF, the tissue specimen is simply housed in the bank and does not become a part of the tumour bank available collection. It should be attempted to get informed consent within 24 months from the time the participant was in for surgery or biopsy. Every reasonable attempt will be made to contact the participant within this time frame. Contact with the potential participant may take place at their routine clinic visit, by mail and/or by telephone. However, this is at the discretion of the local REB. Standard format contact letters will be sent to potential

participants on a quarterly schedule to prompt a response. If at the end of a 24-month period (or shorter if dictated by the local REB), consent has not been obtained, it will be determined, that consent cannot be obtained, the specimen will be removed from the tumour bank and destroyed. At some banks, the REB may determine that the only documentation that will remain on a recruitment database is the indication that they were contacted regarding tumor banking and that they either did not respond or declined. A record that the proper procedure as to specimen removal and disposal was carried out and all other data on this patient were purged from the bank.

7.3.3 Impartial Witness

If the patient is unable to read, an impartial witness (see Definitions) should be present during the entire informed discussion. After the consent form and any other written information is read and explained, the patient can orally consent to participate in the tumour repository program. Both the patient (if capable) and the impartial witness must sign and date 2 copies of the consent form. Indicate on both copies of the Consent Form that the printed name, signature, and date were obtained from the impartial witness.
By signing the consent form, an impartial witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient or the patient's legally acceptable representative, and that informed consent was freely given by the patient or the legally acceptable representative.

7.3.4 Use of Interpreter

If the patient or the legally acceptable witness does not speak the language of the Informed Consent Form, the consent discussion should take place in the patient's language using a qualified interpreter or family member if needed. Both the patient (if capable) and the interpreter must sign and date 2 copies of the Informed Consent Form. Indicate on both copies of the Informed Consent Form that the printed name, signature, and date were obtained from the interpreter.
By signing the consent form, the interpreter attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the patient or the patient's legally acceptable representative, and that informed consent was freely given by the patient or the legally acceptable representative.

7.4 Documenting Informed Consent.

1. File the signed Consent Form in the patient recruitment log. Include the following information:
   - Date that informed consent was obtained
   - Whether a translator, legally acceptable representative or impartial witness was used
   - Who obtained the consent

- Date consent was obtained

2. Register consent status with the repository's inventory database.

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, Oct. 2005 version. Section 10. 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.

