CTRNet Standard Operating Procedure Developing and Revising Consent Forms			
SOP Number:	02.002	Version:	e2.0
Supersedes:	2.1.002 e1.0	Category:	Participant Recruitment and Management

Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	29-MAY-2012

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 biobank program. Participants consent to donate tissue (surplus to the needs of the pathology department to the tumour biobank) 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

This standard operating procedure (SOP) covers the procedures for developing and revising consent forms. The SOP covers basic elements of the consent form, 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 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 02.007 Notification of Significant and Relevant Findings*

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank personnel, clinical and research staffs at the collection centres that are involved in developing and revising consent forms. This may include the following personnel:

Tumour Biobank Personnel	Responsibility/Role
Tumour Biobank 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

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

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:

7.1.1 Objectives of the tumour biobank program. A statement as to the goals of the research for which the specimens will be used should be stated. The consent should cover expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

7.1.2 A description of any reasonably foreseeable risks or discomforts to the subject. Cover relevant risks such as those associated with giving blood that may include bruising, bleeding and infection at the site. Include risks associated with making information from health records available to the tumour biobank but specify measures that will be taken to protect privacy and confidentiality.

7.1.3 A description of any benefits to the participant or to others that 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 general benefits such as the development of new tests and therapies for cancer. Individual data if generated will not be made available to the patient except in the rare case when the

clinical usefulness of the data becomes medically significant, and this only after specific issues have been considered and measures have been undertaken (refer to *SOP 02.007 Notification of Significant and Relevant Findings*)

7.1.4 A statement describing the extent to which confidentiality of records identifying the subject will be maintained. Provide assurance that reasonable measures will be taken to protect confidentiality of data and identity.

7.1.5 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.

7.1.6 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.

7.1.7 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.

7.1.8 Include direction and contact information indicating whom the participant can contact if they wish to revoke consent.

7.1.9 Mention policies and specific details that are pertinent to the release and sharing of samples. These may include whether samples will only be shared within academic institutions, or whether they are available more broadly. It may spell out conditions for sample release, including the need for each research project to have undergone REB approval

7.1.10 An indication of the possibility that the patient could be contacted at a later date and the reasons for such contact, such as to obtain additional information or to provide general information about the research supported by the biobank, or to offer participation in a relevant research study. Contact for other purposes will only 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:

7.2.1 Safety reports or review following complaints mandate change.

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

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

7.2.4 There are amendments to the tumour biobank program.

7.2.5 The REB recommends change.

7.2.6 Local and institutional identifiers need to be inserted.

7.3 Legal and Cultural Language to be Used in the Consent Form

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

7.3.2 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.

7.3.3 Do not use language that releases or appears to release the tumour biobank, the investigator, the research sponsor, the institution or its agents from liability for negligence.

7.3.4 Tailor consent forms to address the situation in which the consent is being obtained (pre-procedure and post-procedure consent).

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

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

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

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

7.4 REB Approval of Consent Forms

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

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

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

9.1 Appendix A – CTRnet Consent Form Templates (when developed)

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.002 e1.0	Aug 2008	JdSh	Initial release
2.1.002 e1.0	Apr-2012	CMG	• Grammatical and formatting updates throughout. • Definitions removed. • Reference links updated. • Section 2 (Scope): deleted “the SOP covers preferred legal and cultural language that should be used,” Section 7.1: #1, changed wording. #8, deleted “Describe what will take place should consent be withdrawn”, #9, worded more specifically, deleted #10