


| CTRNet Standard Operating Procedure Obtaining Informed Consent | | | |
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| Category: | Participant Recruitment and Management | | |
| SOP Number: | 02.005 | Version: | e2.1 |
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| 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 vital for the ethical conduct of the tumour biobank program. Participants consent to donate their tissue (typically material that has been determined to be excess to requirements for diagnosis and future care after a scheduled surgical treatment or medical procedure) and/or other biological specimens (e.g. blood sample) to the tumour biobank, allow access to their clinical records, acknowledge that they accept associated risks (e.g. risks of phlebotomy and/or loss of privacy) and give permission for these materials (specimens and data) to be used for broadly specified future research. Consent is usually accompanied by a commitment from the biobank that governance of the collection and storage and use of their materials will include review by an independent Research Ethics Board (REB) of the tumour biobank itself and of each research application to use the materials.

2.0 SCOPE

This standard operating procedure (SOP) covers the procedures for obtaining and documenting informed and voluntary consent from a donor to participate in a tumour biobank program. It lists in step-by-step format, the appropriate tasks and procedures that must be followed at the step of obtaining consent. Related steps, tasks and procedures are covered in other SOPs. These steps may be adopted as is, or modified by 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 02.001 Participant Recruitment into a Tumour Biobank Program

4.0 ROLES AND RESPONSIBILITIES

This SOP applies to all qualified tumour biobank 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 Biobank Personnel | Responsibility/Role |
|--|--|
| Tumour Biobank Manager, Director, or Principal Investigator | Developing an appropriate recruitment plan in conjunction with Oncology physicians (surgeons/oncologists) at the cancer centre/hospital or their designate |
| Clinical Research Coordinator (CRC)/Biobank Nurse/Appropriately trained consenting personnel | Obtaining and documenting informed consent and identifying patients for 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

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. The form must contain relevant information. It may also serve as a reference for discussion points that should be covered during the consent process. REB approved information attached to the Informed Consent Form also serves as an ongoing reference for participants.

7.1 General Informed Consent Guidelines

7.1.1 Prior to starting the consent process with a patient, review CTRNet Policy *POL 1 Informed Consent*. This will provide a basis for ethical considerations that should govern the process. Also review *CTRNet SOP 02.001 on Participant Recruitment into a Tumour Biobank Program*. This provides the wider context of the processes within which the informed consent process occurs.

7.1.2 Keep in mind that the rights, safety and well being of research participants are the most important consideration and should prevail over the interests and the goals of the biobank, 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 biobank program.

- 7.2.1 After receiving a referral through an appropriate mechanism and ascertaining/confirming the initial interest of the participant and/or appropriateness of the referral for the biobank (see CTRNet SOP 02.001 *Participant Recruitment into a Tumour Biobank Program*), initiate the consent process.
- 7.2.2 Establish (e.g. through direct contact or by telephone) with the potential participant their initial interest and their choice for a meeting to inform them about the tumour biobank program (e.g. time and meeting place). Note that the potential participant should be free to choose and may choose other mechanisms (e.g. to receive materials by email or mail and to discuss by telephone) but a face to face meeting is usually the optimal setting.
- 7.2.3 Ensure that the Informed Consent Form with any additional REB-approved information on the tumour biobank program is a current REB approved version and take a copy for the participant and the biobank to the meeting
- 7.2.4 For the purpose of the consent discussion, meet the participant in a space that offers, if possible, a quiet and private environment.
- 7.2.5 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.
- 7.2.6 Initiate rapport with the patient and assess whether or not the patient is competent to consent to participate in the tumour biobank 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 should be questioned, if these circumstances exist, a second opportunity to meet at the participant's request may be offered and a decision and signature should be deferred.
- 7.2.7 Using the Informed Consent Form as a guide, give the patient information (in clear language) about the following:
 - a. Objectives of the tumour biobank program.
 - b. Confidentiality issues. Reinforce that the discussion is confidential. Provide assurance that confidentiality of data and identity will be protected. Describe in general lay terms processes and steps taken by the biobank to protect confidentiality.
 - c. Outline any procedures the patient may be invited to undergo to participate (e.g. phlebotomy) and procedures (e.g. surgery) that are part of clinical treatment that may offer an opportunity for participation.
 - d. Describe how the tissue sample, blood, other biological material, and data will be handled and stored.
 - e. Discuss the risks of participation in the program. Mention risks associated with giving blood that may include bruising, bleeding and infection at the site. Cover risks associated with making information from health records available to the tumour biobank but specify measures (such as coding) that will be taken to protect privacy and confidentiality.

Obtaining Informed Consent

- f. 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 normally be made available to the patient.
 - g. 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.
 - h. Clarify that participation is voluntary. The decision to decline to participate now or to withdraw from the program at any future date, will not affect the standard or type of care the patient will receive.
 - i. Provide information about the governance, purpose and intended users of the biobank.
- 7.2.8 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. Identify contact information for the tumour biobank that should be included in the consent form so that the patient can obtain additional clarification or ask further questions.
- 7.2.9 If the patient agrees to participate in the tumour biobank program, request that the patient sign and date one or more copies of the Informed Consent Form as per institutional policy.
- 7.2.10 The individual obtaining the consent and/or the biobank representative should sign and date one or more copies of the Informed Consent Form as per institutional policy.
- 7.2.11 Provide one copy of the completed Informed Consent Form (along with attached REB approved information) to the participant and retain one or more copies for the tumour biobank program records or for other locations as required by institutional policy.

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 can be sought. Follow the procedures described in Section 7.2 above, but instead obtain the signature of the Legally Acceptable Representative. Indicate on both copies of the Informed Consent Form that the printed name, signature, and date were obtained from the Legally Accepted Representative. Some biobanks, after consultation with their REB, may decide not to obtain consent by this method.

7.3.2 Impartial Witness

If the patient is unable to read, an impartial witness should be present during the entire informed discussion. After the Informed Consent Form and any other written information is read and explained, the patient can orally consent to participate in the tumour biobank program. Both the patient (if capable) and the impartial witness must sign and date one or more 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 impartial witness.

By signing the Informed Consent Form, an impartial witness attests that the information in the Informed 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.

7.3.3 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 one or more 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 Informed Consent Form, the interpreter attests that the information in the Informed 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

7.4.1 File the signed Informed Consent Form in the patient recruitment log. Include the following information:

- a. Date that informed consent was obtained
- b. Whether a translator, legally acceptable representative or impartial witness was used
- c. Who obtained the consent
- d. Date consent was obtained

7.4.2 Register consent status with the biobank's inventory database.

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/clin-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 Perun, H., Orr, M., Dimitriadis, F. Guide to the Ontario Personal Health Information Protection Act. 2Irwin Law Inc., 2005; p.650.

9.0 APPENDICES

None

10.0 REVISION HISTORY

| SOP Number | Date revised | Author | Summary of Revisions |
|--------------|--------------|------------------------|---|
| PC 101.001 | 2005 | JdSH | CTRNet Generic SOP for Obtaining Informed Consent. |
| 2.1.005 e1.0 | Aug 2008 | JdSH | Minor formatting changes and reviewed to reflect current practice at the member banks. |
| 2.1.005 e1.0 | Feb 2012 | CMG | <ul style="list-style-type: none"> • Grammatical and formatting updates throughout. • Section 1: (Purpose), The entire paragraph has been re-worded. (Additions & deletions) • Section 2: (Scope), re-worded • Section 3: (References), added #4, SOP Participant Recruitment • Section 4: (Roles) Used the same wording as SOP # 02.001 • Definitions removed • Section 7.1: (Consent Guidelines), deleted "Consent may be obtained in a prospective or retrospective manner...In both situations, the following procedures apply:" added a sentence to say review the SOP on Participant Recruitment. • Section 7.2, whole section re-worded. • Section 7.3, re-worded • Section 7.4, minor changes • Reference links updated • Revision History section moved to bottom • Removed definitions |
| 02.005 e2.0 | Jan 10 2013 | AJS as per B. Schacter | Removed 7.4.1 (d). "Date consent was obtained". This is redundant. |
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