Title	Informed Consent Process for Biorepositories
SOP Code	SOP104_02
Effective Date	04-Jan-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for obtaining and documenting initial and ongoing voluntary informed consent from a participant in the biorepository program. This SOP also describes informed consent guidelines, and the roles of the legally acceptable representative and impartial witness.

It does not apply to obtaining informed consent from minors or to exceptions to informed consent requirements for emergency situations.

2.0 SCOPE

This SOP is applicable to all efforts undertaken at the site for the biorepository program, and to those biorepository personnel responsible for performing, reviewing, and/or approving the informed consent process.

3.0 RESPONSIBILITIES

The biorepository Director is responsible for ensuring that the team under his/her supervision complies with the informed consent process described in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Obtaining Prospective Informed Consent

5.1.1 Ensure that the person obtaining informed consent is qualified by training to do so, and is knowledgeable in the biorepository procedures.

5.1.2 In obtaining and documenting informed consent, the qualified personnel should comply with Good Clinical Practice (GCP) and with the ethical principles of the Declaration of Helsinki and the Tri-Council Policy Statement, where applicable.

5.1.3 Prior to the beginning of the program at the collection site, the Director must have written Research Ethics Board (REB)/ Independent Ethics Committee (IEC) approval of the informed consent form and any other written information to be provided to participants.

5.1.4 Review the biorepository details with the participant, preferably in a quiet, private location. Do not coerce or unduly influence a participant to participate, or to continue to participate in a biorepository program.

5.1.5 Assess the participant's competence to consent to research, and document if the participant is deemed not competent to consent.

5.1.6 Fully inform the participant of all pertinent aspects of the biorepository procedures and associated information (i.e., all essential elements as described in the ICF), including any additional REB/ IEC-approved written information, in non-technical language that is easy for the participant to understand. These may include:

- Objectives of the biorepository program
- Confidentiality issues. Reinforce that the discussion is confidential.
- {Describe the extent to which confidentiality of records identifying the participant will be maintained}
- Provide assurance and describe the extent to which confidentiality of data and identity will be protected.
- Outline procedures the patient will have to undergo.
- Describe how the tissue, 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 biorepository 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 biospecimen 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.

5.1.7 Provide the participant with a copy of the ICF (ensure that the most recent version of the REB/IEC-approved ICF is used), and any other REB/IEC-approved written information. Allow the participant ample time to read the informed consent form and ask questions. This may include taking the ICF home to review with a family member, or other trusted individual.

5.1.8 Ask the participant questions to assess his/her comprehension of the material reviewed. Ensure that he/she fully understands the information.

5.1.9 Ascertain the participant's willingness to participate. Document the decision of any participant who declines to participate.

5.1.10 Inform the participant that he/she may withdraw consent at any time. Inform the participant that this may include withdrawal of his/her data and human biological materials. Any circumstances that do not allow withdrawal of data or human biological materials once collected shall be clearly explained to the participant.

5.1.11 Request that the participant sign (and initial, if required) and date the ICF in the indicated places. Sign and date the ICF as the person who conducted the informed consent discussion. Obtain any other signatures/dates, as indicated on the ICF. All required signatures in prospective informed consent procedures should be obtained prior to enrolling the participant into the biorepository program.

5.1.12 Provide the participant with a photocopy (or similar) of the signed document, and any other REB/IEC-approved written information reviewed during the informed consent discussion.

5.1.13 File the original signed ICF in the appropriate location, such as the participant

chart or equivalent location.

5.2 Obtaining Retrospective Informed Consent

5.2.1 Retrospective signing of the informed consent requires a potential participant to give permission for biobanking after the biospecimen has been removed from the body and is being temporarily stored in the biorepository facility.

5.2.2 Until the potential participant signs the ICF, the biospecimen is simply housed in the biorepository but does not become a part of the available collection.

5.2.3 Every attempt will be made to get informed consent from the patient within a reasonable amount from the date of surgery.

5.2.4 Contact with the potential participant may take place at his/her routine clinic visit, by mail and/or by telephone. However, this is at the discretion of the local REB.

5.3 Ongoing Informed Consent

5.3.1 Ensure that the participant's consent to participate in the biorepository program remains valid by providing ongoing opportunities for the participants to ask questions about the program.

5.3.2 Communicate any important new information that becomes available, and that may be relevant to participant's consent, in a timely manner. This communication should be documented in the participant's chart or equivalent documents.

5.3.3 Revise the ICF (and any other written material), and submit to the REB/IEC for approval (refer to specific SOP/s for REB/IEC submission process).

5.3.4 Re-consent the participants affected by the changes, after REB/IEC approval is obtained (if required).

5.3.5 Provide copies of the revised ICF and any other REB/IEC-approved written information to the participant/s.

5.3.6 File the original signed revised ICF with the biorepository program-related essential documents (participant chart or other).

5.4 Participants Unable to Speak English

5.4.1 If the participant does not speak English, ensure that the informed consent discussion takes place in the participant's first/preferred language, using a qualified interpreter.

5.4.2 Obtain an REB/IEC-approved translated consent form, if possible.

5.4.3 Obtain the dated signatures of both the participant and the interpreter on the REB/IEC-approved consent form. 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 participant, and that informed consent was freely given by the participant.

5.4.3 Distribute and file documentation, as described above.

5.5 Participants Unable to Read

5.5.1 If a participant is unable to read, an impartial witness must be present during the entire informed consent discussion.

5.5.2 Obtain verbal consent from the participant, after the ICF any other written information is read and explained to the participant.

5.5.3 Obtain dated signatures from both the participant (if capable), and the impartial witness on the ICF, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant.

5.5.4 Distribute and file documentation, as described above.

5.6 Documenting the Informed Consent Process

5.6.1 Record evidence of the informed consent process in the source documentation, including statements of:

- The participant's comprehension of the material reviewed;
- The participant having been given ample opportunity to read the informed consent form and to decide whether or not to participate in the biorepository program;
- Adequate time having been given for all questions about the biorepository program; to be answered to the satisfaction of the participant; and
- Any other relevant information involving the process of informed consent.

5.7 Withdrawal of consent

5.7.1 In the event that a participant wishes to opt-out of the program, the qualified biorepository personnel will fully inform the patient about this procedure. Allow the patient ample time to ask questions. It is recommended that the patient comprehends the opt-out process before withdrawing consent.

5.7.2 The person who conducted the opt-out discussion must document, sign, and date the withdrawal of consent.

5.7.3 If the participant withdraws consent using a separate REB/IEC-approved form, provide the patient with one copy of the signed and dated form (a photocopy is acceptable); one copy will be retained with biorepository program files and a copy may be filed with the participant medical record if required by the institution.

5.8 Follow-up action after Withdrawal of Consent

Deleting information for revoked consent when tissue has not been processed:

5.8.1 Upon receipt of withdrawal of consent all unused biospecimens from the participant remaining in the biorepository must be removed. Keep a log of all removed samples from revoked consent participants.

5.8.2 Delete all electronic data and anonymous data and destroy (shred) hard copies of Personal Identifying Data, excluding original signed consent forms. Do not collect any additional information about the individual from any source.

5.8.3 Should a back-up of the inventory system or database ever be restored, then the Director should ensure that identifying records stored on the removed samples log are deleted from the records again.

Deleting information for revoked consent when materials have been released:

5.8.4 If biospecimens were released for research before consent was withdrawn, do not take any action to recover the samples.

5.8.5 Delete all electronic data and destroy (shred) hard copies of Personal Identifying Data, excluding original signed consent forms. Do not collect any additional information about the individual from any source.

5.8.6 Retain Anonymous Data, which has been released to researchers, including diagnosis, gender, age at diagnosis, race, de-identified clinical documents and

questionnaire. Only anonymized data for the previously released biospecimens and processed products may be used for future research after consent has been revoked.

5.8.7 Should a back-up of the inventory system or database ever be restored, then the Director should ensure that identifying records stored are deleted from the records again.

5.9 Requesting Additional Information

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

5.9.2 Strive to collect and store all relevant clinical data associated with a biospecimen to maximize the use of biospecimens for current, future and longitudinal studies.

5.9.3 Maintain the ability to store identifying information and contact information for biospecimens as permitted under law and by participant consent to enable biospecimen use for longitudinal studies or outcome research.

5.9.4 Ensure that participant privacy is safe-guarded.

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

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

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

5.9.8 Establish local written procedures to facilitate follow-up with the participants in the event follow-up is needed.

5.9.9 Only have qualified biorepository personnel submit the request for additional data or contact participants.

5.9.10 Document clear rationale for collecting additional information and specify the value it will provide.

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials

Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD. http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. 3rd Edition, http://www.isber.org

CTRNET Standard Operating Procedures, Canadian Tissue Repository Network,

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP104_01	01-Aug-2012	Original version
SOP104_02	04-Jan-2016	5.1.6: Clarification added. 5.8.2: Extended destruction to anonymous data. 5.9.8 Clarification of instructions. Updated references. Removed OTRN logo.