Title	Informed Consent Forms for Biorepositories
SOP Code	SOP103_01
Effective Date	01-Sep-2012

Site Approvals

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

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the activities involved in preparing the Informed Consent Form (ICF), including essential elements of the ICF document; writing, reviewing and/or modifying an ICF; legal and cultural language considerations in the ICF document; and Research Ethics Board (REB)/Independent Ethics Committee (IEC) approval considerations.

This procedure also applies to other written material supplied to the participant, which may contain the same information, as included in the ICF.

2.0 SCOPE

This SOP is applicable to all biorepository personnel responsible for drafting, adapting, revising or reviewing the ICF.

3.0 RESPONSIBILITIES

The biorepository Director is responsible for ensuring that the ICF meets all of the applicable regulatory and local requirements.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Guidelines

5.1.1 The ICF is developed, adapted, or revised by the designated staff member, and should be approved by the biorepository Director before submission to the REB/IEC.

5.2 General Informed Consent Form Guidelines

5.2.1 Use language that is as non-technical as possible, and understandable to the participant, without compromising the content. An eighth grade reading level is recommended.

5.2.2 Define all medical and technical terms and acronyms, common initials, and other abbreviations when first used.

5.2.3 Use headings, bulleted lists, and visit activity charts, and avoid dense paragraphs, in order to improve readability and assist comprehension.

5.2.4 Select a font size appropriate to the target population considering such factors as age and underlying conditions, when possible, unless otherwise specified by the REB/IEC.

5.2.5 It is recommended to have someone unfamiliar with the biorepository processes, preferably a lay person, read the ICF and other written materials. This allows an assessment of comprehension of the material. Make adjustments to the content, as necessary.

5.3 Development of Informed Consent Form: Content

Ensure that the ICF includes the information described below, when developing or adapting an ICF template.

5.3.1 Include all of the essential elements (required and additional), using an ICF checklist, or provided in applicable guidelines:

- Objectives of the biorepository 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 participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant. 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 biorepository, but specify measures that will be taken to protect privacy and confidentiality.

- 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 participant, except for in the rare case when the clinical usefulness of the data becomes medically significant.
- A statement describing the extent to which confidentiality of records identifying the participant will be maintained. Provide assurance that confidentiality of data and identity will be protected.
- An explanation of whom to contact (such as a participant representative) for answers to pertinent questions about the research and research participants' rights, and who to contact in the event that the participant wishes to express a concern or complaint.
- Specification that the participant will not receive any compensation for participation in the program. The participant will also have no share in any revenue generated from any tests, therapies or discoveries generated from research on the tissue or data.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of treatment to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of medical care to which the participant is otherwise entitled to.
- Discussion of consent withdrawal, and any limitations or conditions on withdrawal, such as any circumstances that do not allow withdrawal of data or human biological materials once collected, and secondary use of identifiable information.
- A description how the tissue sample, blood and data will be handled, stored, and released to researchers.
- A clear statement informing the participants what participation in the biorepository program will mean for them. Consistency with the biorepository policies and procedures (e.g., number of visits, inclusion/exclusion, procedures, expected risks, etc.).
- An indication of the possibility that the participant could be contacted for additional information at a later date. Contact will be made at the discretion of the REB/IEC.

5.3.2 Ensure that the ICF meets all applicable regulatory, local, and REB/IEC requirements.

5.3.3 Number all pages.

5.3.4 Include ICF version number and/or date on each page.

5.3.5 Print ICF is printed on local letterhead.

5.3.6 Translate the ICF into appropriate language/s, using a qualified translator, when required. Forward translations to the biorepository Director for approval, prior to submission to the REB/IEC. Refer to local REB/IEC for specific requirements for translation of informed consent and other participant documents.

5.4 Revisions to the Informed Consent Form

5.4.1 Revise the ICF, as needed, based on recommendations from the REB/IEC and/or regulatory authorities, international, national, local or institutional ethical and safety guidelines or relevant changes to the biorepository program.

5.4.2 Clearly identify each ICF version with the version number and/or date on each page.

5.4.3 Submit ICF revisions to the biorepository Director for review, prior to submission to the REB/IEC (when applicable).

5.4.4 Submit the revised ICF with the changes to the REB/IEC for approval.

5.4.5 Do not begin using the revised ICF until written approval is received from the REB/IEC.

5.4.6 Maintain a record/audit trail of all communications related to the ICF revision (communications with regulatory authorities, REB/IEC, etc.)

5.5 Waiver of Participant's Legal Rights

5.5.1 Do not use any language in the ICF that causes the participant, or their legally acceptable representative, to waive, or appear to waive, any legal rights.

5.5.2 Do not use any language in the ICF that releases, or appears to release, the biorepository, the institution, the site, the Sponsor, or their agents from liability for negligence. Statements such as, *"we are not responsible for …"* must be avoided.

5.6 Cultural Considerations (Non-English/Non-French Populations)

5.6.1 Prepare or obtain an ICF in the foreign language/s, as required. Ensure that the

language respects the culture, traditions, and knowledge base of the cultural group being invited to participate in the biorepository program.

5.6.2 Forward translations to biorepository Director for approval, prior to submission to the REB/IEC (refer to local REB/IEC for specific requirements for translation of informed consent and other participant documents.)

5.7 REB/IEC Approval Considerations

5.7.1 Obtain approval from the biorepository Director and the REB/IEC before implementing any revised ICFs. The only exception is in emergency situations (immediate safety hazard to participants), or as covered under exceptions to informed consent process.

5.7.2 Do not begin using the revised ICF until written approval is received from the REB/IEC.

5.8 Participant Re-consent

5.8.1 Re-consent participant whenever important new information becomes available that may be relevant to the participant's consent to continue in the biorepository program. Retain signed original hard copies of all ICF versions signed. Give copies to participants.

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. Cell Preservation Technology 6(1), 3-58, 2008 http://www.isber.org/Pubs/BestPractices2008.pdf

CTRNET Standard Operating Procedures, Canadian Tumour Repository Network, http://www.ctrnet.ca/operating-procedures

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP103_01	01-Sep-2012	Original version