Title	Standard Operating Procedure (SOP) Administrative Management
SOP Code	SOP001_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 process for the development, review, approval, and maintenance of written SOPs intended for use at all clinical research sites and/or biorepositories.

2.0 SCOPE

The SOPs are made available to sites for its constituents to follow for the conduct of clinical research and/or collection of biospecimens. It is up to the site to adopt the Biospecimen SOPs.

3.0 RESPONSIBILITIES

The Biospecimen SOP Committee is responsible for developing and maintaining the set of SOPs according to this SOP. Each institution or biorepository must identify a person or person(s) responsible for implementation of the SOPs at the clinical research site and/or biorepository.

The Biospecimen SOPs must be in compliance with Good Clinical Practice regulations, guidelines, and related documents, as applicable.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Information

5.1.1 Follow the outline below, if the institution requires additional SOPs beyond the Biospecimen set. IMPORTANT NOTE: Changes to any SOP subject content may invalidate the compliance status of the SOP.

5.1.2 Write Biospecimen SOPs according to a standard format, as described below. If sites must write local SOPs beyond the Biospecimen set, use the same format, unless unable to use this model, due to specific institutional requirements (e.g., different font or institutional letterhead/logo). If so, include a note in the SOP file explaining the circumstances.

5.1.3 Prepare original and revised SOPs in a standardized electronic format, using the formatting, font (Arial 14 for headings, Arial 12 for body text) and writing style, as shown in the standard SOP template.

5.1.4 Format headers and footers, with described information, as shown in the current approved template. Number all SOP and appendix pages in the bottom right corner of the footer of each page, e.g., Page x of y.

5.1.5 Use the date format: day in two digits (dd), month in three letters (Mon), and year in four digits (yyyy).

5.1.6 Reference to the masculine gender indicates either gender.

5.1.7 Use the active voice and present verb tense, as much as possible.

5.1.8 Use titles and/or functions, not individual names.

5.1.9 Flow charts, tables, and diagrams may be used in SOPs, as needed.

5.1.10 SOPs must contain authorized approval signatures before use. The approved and signed version is the only official version.

5.2 SOP Content

5.2.1 Title section: Include the following:

- The complete title, without any abbreviation, clearly describing the SOP.
- SOP Code: ‘SOP’, followed by the corresponding SOP in three digits (000 series = general SOPs for clinical trials and biorepositories, 100 series = SOPs for biorepositories, and 200 series = SOPs for clinical trials),

underscore(_), then consecutive major version numbers in two digits, e.g., SOP001_01 is version 1 of SOP001, SOP001_02 is version 2 of SOP001; use minor version number updates for minor typographical errors/clarification, or other administrative changes, e.g., SOP001_03.1 contains a minor update from SOP001_03. The effective date remains the same as the last major revision.

- Effective Date refers to the date that the SOP was approved by the Biospecimen SOP Committee.

5.2.2 Site Approval: Include the following:

- Name and title of person/s involved in the approval process of the SOP at the site;
- Print names in block letters. Sign and date; and
- Attach page for additional signature block, if necessary.

5.2.3 Complete the SOP Revision History section following the first approval of the SOP, and include the following:

- SOP Code, including version number;
- Effective date of the final version in the standard date format;
- A description of any changes in the version referred to; and
- Start with “SOPxxx_01” and “original version”.

5.3 Section Numbering

5.3.1 Number SOP sections and include specific information, as follows:

1.0 Purpose: (what does SOP describe)
2.0 Scope: (what department/area and people does this apply to?)
3.0 Responsibilities: (who performs/reviews the tasks)
4.0 Definitions: (optional, if you have a glossary)
5.0 Procedure: (how procedure is done; use active/assertive verbs and sentences, if possible, e.g., “Obtain signature …; Complete CRF …; File document …”
6.0 References
7.0 Revision History: (describe changes made as new versions are created. First entry is called “1.0 original version”. Use a table format to present this information.)

5.4 Duties of the Biospecimen SOP Committee

- include committee members representative of the research teams using the SOPs;
- develop new and review existing SOPs, using this procedure;
- designate one or more individuals, qualified by experience, skills, and

training, to draft a new or revised SOP;
- remain current on clinical trial regulations and guidelines, research practice, or institutional policies;
- schedule and conduct review of every SOP, at least once every two years, or sooner, if there are changes to regulations, guidelines, etc.;
- ensure that SOPs are created or updated, as needed, to reflect any changes to regulations, guidelines, research practice, or institutional policies; and
- maintain central SOP files and control access to the SOP documents.

5.5 Initiate New or Revised SOPs

5.5.1 Any clinical research site or biorepository personnel can identify the need for new/revised SOPs, based on findings from a scheduled SOP review, audit, or changes to regulations, guidelines, research practice, or institutional policies.

5.5.2 The designated writer/trainer writes the original SOP following the standard format, or amends (if possible) the previously approved SOP, according to this procedure.

5.6 Bi-Annual SOP Review

5.6.1 Review every SOP, no less often than every two years, but more frequently, if changes are required.

5.6.2 Document review. Record required changes (if any) OR 'bi-annual review, no revisions needed' (or similar statement) in the Revision History section of the SOP. Complete the SOP Revision Summary Record for each document. Update to next version number and effective date.

5.7 Approval, Training, and Implementation of SOPs at Sites

5.7.1 Biospecimen SOP Committee: Post each approved SOP on the designated site, i.e., thereby making it available to the designated person/s responsible for SOP approval at the site.

5.7.2 Site representative: Obtain signed and dated approval.

5.7.3 Site representative: Ensure that training is provided to staff members for new and revised SOPs, as required. Note: The trainer must be qualified by a suitable combination of education, experience, and skills. Complete training prior to implementation of the SOP (or at least, before the individual performs the described tasks). Document the training.

5.8 Management, Distribution, and Storage of SOPs

5.8.1 Store the electronic copy of each current approved version of each SOP (e.g., MS Word). Establish back-up procedures for electronic files.

5.8.2 Ensure that current SOP copies are readily available to all clinical research and/or biorepository staff. Copies of the SOPs are permitted for internal use.

5.8.3 Post electronic SOPs in a read-only format, e.g., pdf.

5.9 Management, Distribution, and Storage of SOPs at Sites

5.9.1 Ensure that current SOP copies are readily available to all clinical research and/or biorepository staff. Copies of the SOPs are permitted for internal use.

5.9.4 Ensure that internal procedures are in place to allow adequate and timely training and distribution of the SOPs. Prepare guidelines for the management of the internal circulation of SOPs at the site.

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
SOP001_01	01-Sep-2012	Original version