Title	Document Quality and Care for Biorepositories
SOP Code	SOP105_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 general procedures that can be used to ensure the quality of biorepository documents.

2.0 SCOPE

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

Maintaining well-organized, complete and accurate documentation of all biorepository activities is vital to the operation of a successful biorepository. Timely collection and filing of all required documents also assists in the efficient management of tissue samples and information. All records must be accurate, indelible, legible and retrievable.

3.0 RESPONSIBILITIES

All institutional personnel working in the biorepository program are responsible for following the general procedures that can be used by biorepositories to ensure that samples are labeled and tracked efficiently.

The biorepository Director is responsible for ensuring that the team under his/her supervision complies with all applicable regulations, policies, and procedures.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 General Information

5.1.1 Create a logical, organized filing system that allows for rapid retrieval of program documents.

5.1.2 Record, process, and store all biospecimen information in a way that allows its accurate reporting, interpretation, and verification.

5.1.3 Ensure the integrity and tracking of all biospecimen data through procedures for collecting, capturing, controlling, verifying, correcting, and processing data.

5.1.4 Establish and maintain appropriate authorizations for access to biospecimen data within the biorepository, whether physical or electronic.

5.1.5 Store essential documents in a binder or file box in a secure location (e.g., a locked cupboard of file cabinet) in accordance with all applicable regulations, policies, and procedures. Add institutional storage specifics.

5.1.6 Protect the confidentiality of all participant records (e.g., recruitment logs, Informed Consent Forms) and store in a secure location in accordance with all applicable regulations, policies, and procedures.

5.1.7 Create a separate reference location to store documents, SOPs, Policies, published papers etc. Store SOPS so that they are easily accessible to relevant personnel.

5.1.8 Routinely update all documents to reflect current information and status.

5.1.9 Archive all documents relating to consented participants as required by the REB and /or scientific needs and in accordance with applicable regulations.

5.2 Good Documentation Practices

5.2.1 Observe the following data entry practices:

- Use permanent ink; entries must be legible;
- Enter data in a sequential manner, without leaving any empty spaces;
- Sign and date entries (authorized person/s only);

- Include both data collection and data entry dates, for data obtained after a visit (late data);
- Do not insert late data between existing lines or in the margin. Record data following other entries, with the notation of late entry;
- Data entered by several team members: sign and date each entry corresponding to the authorized person who made the entry;
- Clearly report missing elements (e.g., visit or tests not conducted) in the source document; and

5.2.2 Make corrections to source data as follows:

- Do not use liquid corrector or correcting material;
- Draw a single line through the data to be corrected, without obscuring the original data;
- Initial/sign and date corrections, according to the prescribed format; and
- Ensure that changes are made by the person who made the initial entry, or by others authorized to do so.

5.3 Participant File Creation and Maintenance

5.3.1 Open a participant file soon after participant recruitment.

5.3.2 File new documents on an ongoing basis. (Indicate those responsible for ensuring that items are filed appropriately and files are up-to-date.

5.3.3 Obtain approval from the biorepository Director, prior to making any modifications, deleting or destroying any documents, in accordance with all applicable regulations, policies, and procedures.

5.3.4 Document all changes and actions performed on the document.

5.4 Confidentiality and Direct Access to Clinical Data and Source Documents

5.4.1 Participants through informed consent authorize access to their data, in the belief that all verified and collected information will be kept confidential by the biorepository staff, their authorized representatives, auditors, and regulatory inspectors in accordance with all applicable regulations, policies, and procedures.

5.4.2 Carry out data management in such a way as to respect privacy and meet the standards for privacy and confidentially required by the Research Ethics Board (REB)/Independent Ethics Committee (IEC), privacy legislation (Personal Information Protection and Electronic Documents – PIPEDA, and the applicable provincial legislation), Tri-Council Policy Statement, institutional policies and

procedures, confidentiality agreement, and all other applicable regulations, policies, and procedures.

5.4.3 Protect the privacy and confidentiality of participants, as follows:

- Collect data only for REB/IEC-approved research;
- Do not allow identifying information to leave the institution;
- Ensure that electronic devices that are used for biorepository purposes, such as handheld computers and personal digital assistants, do not contain any participant identifiers;
- Retain a signature sheet identifying those who have access, and those who can enter or correct source data.
- Identify participant data by using unambiguous identification codes (i.e., study identifier), that allows identification of all data reported for each participant; and
- Maintain a system, or list, to link participants to their study identifier.

5.5. Document Storage

5.5.1. Store hard copies of approved documents so as to protect them from environmental damage and protect privacy of participants. The use of locked fireproof cabinets and rooms is recommended.

5.5.2 Protect all paper and/or electronic data from deterioration, and accidental damage or destruction, for the duration of the record retention period.

5.5.3. Retain all essential biorepository documents as per applicable federal, provincial, or local regulations and policies.

5.5.4 Record, manage, and store biospecimen information in a manner which will permit the preparation of complete and accurate reports, as well as permit their interpretation and verification.

5.5.5. Store completed forms separate from participant identifying information in a secure area, accessible only to authorized personnel.

5.6. Document Destruction Procedure

5.6.1. Destroy paper documents requiring destruction in a paper shredder, before disposal in the general garbage.

5.6.2. Delete electronic documents in a secure manner.

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
SOP105_01	01-Sep-2012	Original version