Title	Biorepository Team Roles and Responsibilities
SOP Code	SOP101_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) identifies all members of the biorepository team, and defines their roles and responsibilities.

2.0 SCOPE

This SOP pertains to all biorepository personnel.

3.0 RESPONSIBILITIES

All institutional personnel working in the biorepository program are responsible for performing their roles, as described in this document. 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 Roles and Responsibilities of the Director

5.1.1 The Director is responsible for biorepository, team, and space requirements, conformity with the requirements regulatory authorities and of the REB/IEC, and

team training.

5.1.2 Although some of these tasks may be delegated to other qualified staff members, the Director assumes ultimate responsibility for the overall conduct of the biorepository program, and for compliance with all applicable regulations and guidelines. The Director should document the delegation of tasks/duties (see Section 5.3 Documentation of Task Delegation).

5.1.3 The Director should:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the program, meet all the qualifications specified by the applicable regulatory requirements and provide evidence of such qualifications through up-to-date curriculum vitae and all other relevant documentation requested by the REB/IEC and the regulatory authorities;
- Be aware of, and comply with, the applicable regulatory requirements; and
- Permit inspection by the appropriate regulatory authorities, as applicable.

5.1.4 The Director should also ensure that:

- All persons under his/her supervision are adequately informed about the program) and their biorepository -related tasks and roles;
- A written and dated approval from the REB/IEC for the written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements) and any other written information to be provided to subjects has been granted before the program is begun at the site;
- The program is conducted in compliance with the REB/IEC and, if applicable, appropriate regulatory authorities;
- The data reported are accurate, complete, and timely.

5.2 Roles and Responsibilities of Other Parties

5.2.1 Roles and responsibilities of personnel may differ across biorepositories. The biorepository Director is ultimately responsible for delegating tasks, and defining roles and responsibilities for the biorepository team.

5.3 Documentation of Task Delegation

5.3.1 Director: Maintain a list of appropriately qualified persons to whom he has delegated significant biorepository-related tasks. Include the following information:

- Names of team members,
- Sample complete signature and initials of each team member (dated),
- Tasks specification or roles delegated, and
- Start and end dates of delegation.

5.3.2 Record the signatures and initials of all persons authorized to make entries and/or corrections to data collected, in order to permit an evaluation of the quality of the data.

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
SOP101_01	01-Sep-2012	Original version