Title	Biorepository Staff Training
SOP Code	SOP102_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 recommendations for training biorepository staff in the regulations and guidelines governing the collection and management of biospecimen collection.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to site staff involved in biospecimen collection and management.

3.0 RESPONSIBILITIES

The biorepository Director is responsible for ensuring that the team under his/her supervision complies with the qualification and training requirements described in this SOP. All biorepository staff are responsible for participating in all required training, and for understanding and utilizing the training, as dictated by institutional requirements.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Core Training Modules

A core module should deal with general ethical considerations that are relevant for a biorepository program such as:

5.1.1 Ethics - Moral issues associated with the use of Human Biological Materials in Research, Participant consent issues, Role of the Research Ethics Board (REB) in the approval of consent and material release process.

5.1.2 Training in Privacy Legislation **-** With the introduction of new legislation to protect the privacy of individually identifiable personal information, all biorepository staff must understand the obligations imposed by the applicable privacy legislation, and the implications to their day-to-day practice. Data Collection in Canada must comply with the Personal Information Protection and Electronic Documents Act (PIPEDA), unless formally exempted by provincial privacy legislation that has been recognized as substantially similar to PIPEDA. It is therefore important for all biorepository personnel to be versed in privacy legislation requirements and institutional policies.

5.1.3 Training in Best Practices for Record Keeping and Documentation - Instruct personnel about optimal documentation and reporting practices to ensure security, integrity, and accuracy of information and data handled by the biorepository.

5.2 Site-specific Training

5.2.1 The site-specific training may contain information on:

- Occupational health and safety with specific details pertinent to the site.
- Physical security at the site
- Relevant technical procedures applicable to personnel and operations at the site.
- Maintaining records, updating inventories and databases, interfacing with other databases if relevant to personnel at the site.

5.2.2 Provide each person with site-specific policies and SOPs to read and assimilate if relevant to their job function.

5.3 Research Protocol Training, if applicable

5.3.1 Note: Protocol-specific training is required, if the biorepository is involved in a clinical research study .

5.3.2 Director and biorepository team : Undertake a complete review of the protocol and, prior to study initiation, review the biospecimen aspects of the study.

5.3.3 Protocol training associated with biospecimen collection should be provided by the Sponsor or Sponsor-Investigator, or delegate, who is thoroughly familiar with all aspects of the study. This may occur at the site initiation meeting.

5.3.4 During the course of the study, maintain effective communications with all parties involved in the study. Document all study-related communications, including the names of participants, meeting date, summary of discussions and resolutions.

5.4 Standard Operating Procedures (SOP) Training

5.4.1 The purpose of having documented SOPs is to**:**

- provide written guidelines for the performance of biospecimen collection and , if applicable, all aspects of clinical trials;
- promote quality and consistency in processes;
- ensure compliance with applicable regulations and guidelines; and
- facilitate training of new personnel.

5.4.2 Include SOP training in the orientation of new staff members. In addition, all applicable personnel should be trained on new or revised SOPs.

5.5 Documentation of Qualifications and Training

5.5.1 Document all training, retain in the individual's training records. Biorepository personnel must be prepared to demonstrate all training received.

5.5.2 Maintain a master list of training on each SOP in the SOP files, and in individual SOP training records.

5.5.3 Conduct an assessment of the biorepository personnel knowledge of the regulations and guidelines upon hiring, and if possible, at least every two years thereafter. Assessment may include review by senior biorepository staff, administering a quiz, shadowing of staff, and other assessment practices as per local requirement. Retain the type and results of assessment in the training files.

5.5.4 Conduct an assessment of any additional protocol-specific skill requirements prior to activation of each new protocol. Document all training related to qualification of biorepository personnel, and retain with the essential study documents.

5.5.5 Include the following in training documentation: title of the training, name,

training date, the person or organization who provided the training, and a summary of the training. File the training documentation individually for every person, or as one master file.

5.5.6 Director: Maintain a list of appropriately qualified persons to whom significant study-related tasks have been delegated.

5.5.7 Director and delegates: Provide a complete CV, dated and signed, to be kept with the essential documents (available for verification or inspection). Update the CV every two years (at a minimum). Include the following in the CV: record of employment, education, experience, professional qualifications, training received, including clinical study , e.g., GCP, seminars attended, involvement in clinical studies and, if applicable, teaching experience and publications participation.

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
SOP102_01	01-Aug-2012	Original version
SOP 102_02	04-Jan-2016	5.5.3: Added clarification for assessment of knowledge of regulations and guidelines. Updated references. Removed OTRN logo.