Title	Clinical Annotation for Biorepositories
SOP Code	SOP108_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) outlines minimum data that need to be collected for each specimen to ensure that the specimen is of value in current and future research.

2.0 SCOPE

The primary goal of the biorepositories is to facilitate research that can advance the practice of medicine and preventative medicine. Extensive and consistent annotation of the specimens is crucial to the overall value of the banks samples in research.

This SOP applies to biorepository personnel involved in generating, maintaining and managing records and documents associated with clinical annotation within the biorepository program.

3.0 RESPONSIBILITIES

The biorepository Director is responsible for ensuring that the team under his/her supervision complies with the requirements described in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1. Determining the Clinical Data Set

5.1.1. Define the minimal clinical data to be collected for all biospecimens (Note that this set may change over time).

5.1.2. Use harmonized terminology or Common Data Elements to describe data being collected, to facilitate data sharing and universal understanding.

5.2. Collecting and Managing the Clinical Data

5.2.1. Data collection should strive to conform to requirements stipulated by regulatory agencies such as the FDA and Health Canada so that data can be cited and used in drug approval submissions.

5.2.2. Track researchers request for specific data to guide the extent of collection of data in the future.

5.2.3. Collect data, only if informed consent is in accordance with all applicable regulations and guidelines, and Research Ethics Boards (REB)/ Independent Ethics Committees (IEC), and regulatory authorities consent has been obtained.

5.2.4. Have a method of validating data collected to ensure accuracy.

5.2.5. Comply with privacy regulations and participant protection, when linking and annotating samples.

5.2.6. Maintain identifying and contact information in accordance with all applicable regulations and guidelines and as permitted under privacy law to enable the specimen to be useful for longitudinal studies.

5.2.7. Attempt to collect outcome data with tracking of treatment and participant outcomes, if and when required.

5.2.8. Ensure that all personnel involved in or authorized to collect, enter, transfer and validate clinical data are qualified by education and experience to fulfill this responsibility.

5.3. Specific Clinical Annotation

5.3.1 Collect the following data about specimen and participant, if possible. Specimens with an incomplete data set will be useful but for a more limited set of research applications.

- Demographic data
  - Date of birth
  - Race/Ethnicity
  - Place of Birth
  - Occupation
  - Physician
- Lifestyle Factors
- Family History
- Epidemiological risk factors
  - Alcohol Data
  - Smoking Data
  - Environmental and occupational exposure
- Patient's medical history
- Pathology data
- Pertinent diagnostic studies (Biomarkers like PSA etc.)
- Information on initial staging procedure
- Treatment data
  - Type Dose
  - Therapeutic Agent name
- Response to Treatment
- Surgery Data
  - Type of Surgery
  - Margin status
- Yearly Follow-up data/Outcome data
  - Vital status
  - Data such as recurrence data including location, date and quality of life, if applicable.

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
SOP108_01	01-Sep-2012	Original version