CTRNet Standard Operating Procedure Clinical Annotation			
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REVISION HISTORY

SOP Number	Date Issued	Author (Initials)	Summary of Revisions
2.1.006	2008	JdSH	1st Release.

1.0 PURPOSE

Tissue donated to the tumour bank is intended for research studies. The success of genomics research and ultimately personalized medicine depends on the ability to forge a connection between phenotypic clinical data and molecular measurements on samples. The efficient integration of clinical data with scientific results has become critical in determining populations of patients that may best benefit from a new drug or therapy. Standardized and complete data capture provides the best hope for analyzing large data sets, over many institutions and comparison with other similar or collaborative studies. This SOP is intended to outline minimum data that needs to be collected for the sample to ensure that the sample is of value in as many current and future studies.

2.0 SCOPE

The SOP covers the procedures to ensure that consistent and high-quality data is associated with samples in the banks.

These steps may be adopted as is, or modified by specific CTRNet member repositories at their collection sites to allow for the incorporation of site-specific details, local laws and regulations, conditions and REB requirements.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

1. CTRNet Policy: POL 005.001 Records and Documentation
2. CTRNet Policy: POL 005.001 Material and Information Handling

4.0 ROLES AND RESPONSIBILITY

The SOP applies to all qualified tumor bank personnel, clinical and research staff at the collection centers and repositories that are involved in clinical annotation of samples.

Tumour Bank Personnel	**Responsibility/Role**	**Site Specific Personnel and Contact Information**
Tumour Bank or Research Principal Investigator, Tumour bank Director and Consulting Physician	Determining the range of clinical data that will be collected for a sample	
REB	Reviewing and deciding if sensitive clinical data should be collected	
Nurses, technicians and database analysts	Collecting and managing clinical data.	

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	**Materials and Equipment (Site Specific)**
Health records, Pathology Reports	
Patient Questionnaires	
Inventory and specimen database	

6.0 DEFINITIONS

Annotation: Explanatory or extra information associated with a particular biospecimen.

Common Data Elements (CDEs): Annotations that are collected in a uniform manner across multiple institutions that allow sharing of data in a standardized format and are defined in detail using a metadata dictionary.

Participant: An individual (patient or healthy volunteer, if applicable) who participates in the Tumour Repository Program. The terms patient, participant, subject and potential donor may be used interchangeably.

Tumor Bank or Repository: Regional, provincial or local repositories that coordinates the collection, processing, storage and distribution of tumour tissue and associated annotated data; normally derived from consented participants for the purpose of medical research. The term 'bank' and 'repository' is used interchangeably.

7.0 PROCEDURES

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

7.1 Determining the Clinical Data Set

1. Define the minimal clinical data to be collected for all biospecimens (although this set may change over time).
2. Use harmonized terminology or Common Data Elements to describe data being collected to facilitate data sharing and universal understanding.

7.2 Collecting and Management of Clinical data

1. Data collection should strive to conform to requirements stipulated by regulatory agencies such as the FDA so that data can be cited and used in drug approval submissions.
2. Track researchers request for specific data to guide the extent of collection of data in the future.
3. Only collect data if adequate consent procedures are in place.
4. Have a method of validating data collected so as to ensure accuracy.
5. In linking and annotating samples comply with privacy regulations and participant protection.

6. Maintain identifying and contact information as permitted under privacy law to enable the specimen to be useful for longitudinal studies.
7. Attempt to collect outcome data with tracking of treatment and patient outcomes.
8. Use only trained personnel to collect, enter, transfer and validate clinical data.

7.3 Specific Clinical Annotation

If possible collect the following data about specimen and participant. Samples with an incomplete data set will be useful but for a more limited set of research applications.

1. Demographic data
   - Date of birth
   - Race/Ethnicity
   - Place of Birth
   - Occupation
   - Physician
2. Lifestyle Factors
3. Family History
4. Epidemiological risk factors
   - Alcohol Data
   - Smoking Data
   - Environmental and occupational exposure
5. Patient's medical history
6. Patient's cancer history
7. Pathology data
   - Diagnosis data
   - Histology
   - Site, Stage, grade, size
8. Pertinent diagnostic studies (Biomarkers like PSA etc.)
9. Information on initial staging procedure
10. Treatment data
    - Type (chemotherapy, Radiation, Other)
    - Dose
    - Therapeutic Agent name
11. Response to Treatment
12. Surgery Data
    - Type of Surgery
    - Margin status
13. Yearly Follow-up data/Outcome data
    - Vital status
    - Recurrence data including location, date and quality of life

8.0 APPLICABLE REFERENCES, REGULATONS AND GUIDELINES

1. Declaration of Helsinki. http://ohsr.od.nih.gov/helsinki.php3 http://www.wma.net/e/policy/b3.htm
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8. http://www.ich.org http://www.ich.org/UrlGrpServer.jser?@_ID=276&@_TEMPLATE=254
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/food_drug_reg_amend_1024_gcp_tc_e.html
4. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998. http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
5. USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. http://www.fda.gov/oc/gcp/default.htm or www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
6. Fox Chase Cancer Centre, Biosample repository http://web-apps.fccc.edu/psf/repository/request_info_v2.pdf
7. First Generation Guidelines for NCI-supported Biorepositories, Federal Register/ Vol.71, No 82/ April 28, 2006
8. Patel, A. et al. 2005, The development of common data elements for multi-institute prostate cancer tissue bank: The cooperative Prostate cancer Tissue Resource (CPCTR) experience. BMC Cancer, 5:108.

9.0 APPENDICES

None