

CTRNet Standard Operating Procedure			
Job Descriptions, Roles and Responsibilities			
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Prepared By:		Jean de Sousa-Hitzler		
	Signature	Name	Title	ddMmmyy
Approved By:		Peter Geary	CEO	09 Jan 08
	Signature	Name	Title	ddMmmyy
Approved By:				
	Signature	Name	Title	ddMmmyy

REVISION HISTORY

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1. PURPOSE

Personnel are an important part of a tumour repository. Descriptions of roles and responsibilities are important for selecting, hiring and supervising qualified individuals. Tumour bank personnel are encouraged to participate in the banking process in accordance with their professional roles and responsibilities.

The procedures apply to all roles at the tumour bank.

2. SCOPE

This standard operating procedure (SOP) outlines a process that should be followed to ensure that all employees have clear definition of their role and responsibility within the tumour bank.

3. REFERENCE TO OTHER POLICIES and SOPS

1. All CTRNet SOPs define roles and responsibilities.

4. ROLES AND RESPONSIBILITY

Although the head of the tumor bank is responsible for overseeing the tumour bank program, all personnel have defined roles and responsibilities and should be familiar with this SOP. Note roles at some banks may overlap. The roles and responsibilities should be used as a guide to ensure that personnel are qualified by education and training to accomplish their respective jobs.

Tumour Bank Personnel	Responsibility/Role	Site Specific Personnel and Contact Information
Pathology Assistant	See Procedures (section 7)	
Bioinformatics Specialist		
Clinical Research Coordinator/Nurse		
Data Entry Clerk		
Histotology Technician		
Laboratory Technician		
Operating Room Nurse		
Pathology Coordinator/Assistant		
Physicians involved with the Tumor Bank Program (Oncologist, Surgeon, Pathologist)		
Porter		
Research Ethics Board		
Tumor Bank Coordinator/Manager		
Tumour Bank Director		

5. MATERIALS, REAGENTS EQUIPMENT AND FORMS

Materials and Equipment	Materials and Equipment (Site Specific)
Institutional Job Descriptions	
Job Description Form	
Organizational Chart if available	

6. DEFINITIONS

Qualification: A quality, ability or accomplishment that makes a person suitable for a particular task or position.

Education: Refers to degrees, certification, and/or licensing earned as a result of formal schooling or course of study at an institution of higher learning (e.g., M.D., Ph.D., R.N., board certified in a specialized field, medical licenses etc.).

Training: Generally refers to short focused programs on specific topics. (e.g., 2-week training program in research ethics, and/or mentoring by an appropriately educated, trained and experienced professional)

Experience: Includes direct participation in activities that provide additional expertise in a specific area.

7. PROCEDURES

Job descriptions aid in the construction of organizational charts that may be referred to by Management when allocating resources or personnel for operation of the tumour repository.

They may also be used to ensure that tumour bank personnel are appropriately qualified to perform his or her assigned task.

7.1 Procedure for creating job descriptions.

1. A comprehensive and detailed job descriptions should be developed for each position. See form in Appendix 1 for Job Descriptions.
2. **Position Title, Department, and Location.** Provide the title, the department and the location of the position.
3. **Primary purpose of role.** Describe the primary purpose of the position in one or two brief sentences.
4. **Essential functions.** Most personnel perform a variety of duties. Describe the major, or most important functions and responsibilities of the position.
5. **Tumour Repository Responsibilities.** Include all responsibilities that may be relevant for the position.
6. **Qualifications.** Enter minimum education and/or certification required for the position.
7. **Basic Competencies and minimum experience:** Enter basic competencies and minimum work experience required.
8. **Special Skills.** List special skills required.

7.2 List of Roles and Responsibilities

1. ROLE: Information Technology Staff

RESPONSIBILITIES:

- Conducts routine back-up of database according to specific bank plan
- Monitors Access to Informatics System
- Oversees data transmission – Schedules data export, monitors submission status, reviews process logs for errors and makes corrections when needed
- Monitors and implements security policy adopted by the bank
- Uses best practices for computer hardware and software security
- Prepares and sends data records for external use

2. ROLE: Clinical Research Coordinator/Nurse

RESPONSIBILITIES:

- Obtains and Documents Consent
- Communicates with patients to inform them about the tissue bank program
- Communicates with patients if consent is withdrawn
- Draws blood
- Public relations with clinical community. Interfaces with partners in clinical community.

3. ROLE: Data Entry Clerk

RESPONSIBILITIES:

- Creates and maintains filing system for storing confidential records
- Retrieves records when needed
- Enter clinical and pathology data into database
- Files samples in freezer (storage)

4. ROLE: Histology Technician

RESPONSIBILITIES:

- Fixes tissue
- Embeds tissue in paraffin or OCT

- Cuts tissue sections
- Stains sections

5. ROLE: **Laboratory Technician**

RESPONSIBILITIES:

- Fixes tissue
- Embeds tissue in paraffin or OCT
- Cuts tissue sections
- Prepares Tissue Microarrays
- Freezes tissues and derivatives
- Processes Tissue in derivatives such as DNA, RNA and protein
- Processes and separates blood into components and derivatives
- Assesses quality of tissues and derivatives
- Contributes to development of technical SOPs
- Labels and tracks samples
- Records and documents lab processes
- Retrieves and ships samples according to procedure

6. ROLE: **Operating Room Nurse**

RESPONSIBILITIES:

- Communicates to Tumour bank nurse that suitable sample may be available for banking
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7. ROLE: **Pathology Coordinator/Assistant**

RESPONSIBILITIES:

- Primary lead on specimen collection
- Harvests tissue
- Processes tissue in pathology lab
- Communicates to tumour bank personnel that tissue is available for banking
- Performs tasks assigned by the pathologist
- Collects pathology reports about each case

8. ROLE: Physicians Associated with tumour bank program

RESPONSIBILITIES:

- Surgeon resects tissue from patient
- Oncologist communicates to patient about tissue bank program
- Oncologist informs patient about research findings if relevant and significant
- Pathologist decides if tissue is surplus to needs of pathology department
- Pathologist harvests tissue surplus to needs of pathology for tumour bank
- Pathologist examines tissue makes diagnosis
- Pathologist grades tumour
- Pathologist assesses quality of tissue specimen

9. ROLE: Porter

RESPONSIBILITIES:

- Transports tissue and blood samples to tissue bank

10. ROLE: Research Ethics Board Members

RESPONSIBILITIES:

- Assess research studies for compliance to ethical practice
- Assess practices to ensure privacy and patient security is upheld
- Reviews applications for materials and approves material release
- Decides if patients should be contacted regarding research findings.

11. ROLE: Tumour Bank Coordinator/Manager

RESPONSIBILITIES:

- Contributes to the development of SOPs
- Maintains SOPs for the bank
- Coordinates material requests and release
- Coordinates development and maintenance of Informatics System
- Investigates, reports and documents deviations in practice
- Coordinates quality assessment of samples
- Coordinates privacy and security is maintained in tumour bank
- Coordinates training of tumour bank personnel

- Coordinates Inventory verification
- Coordinates operations and Quality Assurance at Tumour Bank
- Selects samples for shipment

12. ROLE: Tumour Bank Director/Head

RESPONSIBILITIES:

- Oversees hiring of tumour bank personnel
- Oversees education and training of tumour bank personnel
- Responsible for approving SOPs
- Oversees material release
- Responsible for Operations and Quality Assurance at Tumour Bank

8. APPLICABLE References, Regulations, and Guidelines

1. Handbook for Good Clinical Research Practice.
http://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf
2. Responsibilities of Tumour Bank Personnel. OCRN SOP AD102.001 Draft version 3.
3. Job Descriptions and Organizational Chart. SOP HRS.001.00 British Columbia Tumour Tissue Repository.
4. Job Summaries, NCIC Clinical Trials Group, Kingston, Ontario.

9.0 APPENDICES

1. Job Description Form

Appendix 1.

Job Description Form.

Position Title:	Incumbent Name:
Department:	
Location:	

Primary Purpose:

1.0 ESSENTIAL FUNCTIONS:

1.

Responsibilities:

Minimum Qualifications:

Basic Competencies & Minimum Experience:

_____	_____
Approved By	Date