**1.0 PURPOSE**

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

**2.0 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 biobank.

**3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES**

*Note: When adopting this SOP for local use please reference CTRNet.*

*Note: All CTRNet SOPs define roles and responsibilities.*

**4.0 ROLES AND RESPONSIBILITIES**

Although the head of the tumor biobank is responsible for overseeing the tumor biobank program, all personnel have defined roles and responsibilities and should be familiar with this SOP. Note that roles at some biobanks 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.

<table>
<thead>
<tr>
<th>Tumour Biobank Personnel</th>
<th>Responsibility/Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology Assistant</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Bioinformatics Specialist</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Clinical Research Coordinator/Nurse</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Data Entry Clerk</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Histology Technician/technologist</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Laboratory Technician/technologist</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Operating Room Nurse</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Pathology Coordinator/Assistant</td>
<td>See Procedures (section 7)</td>
</tr>
<tr>
<td>Physicians involved with the Tumour Biobank Program (Oncologist, Surgeon, Pathologist)</td>
<td>See Procedures (section 7)</td>
</tr>
</tbody>
</table>
5.0 MATERIALS, EQUIPMENT AND FORM

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.

<table>
<thead>
<tr>
<th>Materials and Equipment</th>
<th>Materials and Equipment (Site Specific)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutional Job Descriptions</td>
<td></td>
</tr>
<tr>
<td>Job Description Form</td>
<td></td>
</tr>
<tr>
<td>Organizational Chart if available</td>
<td></td>
</tr>
</tbody>
</table>

6.0 DEFINITIONS

See the CTRNet Program Glossary: [http://www.ctrnet.ca/glossary](http://www.ctrnet.ca/glossary)

7.0 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 biobank.

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

7.1 Procedure for Creating Job Descriptions

7.1.1 A comprehensive and detailed job description should be developed for each position. See form in Appendix A for Job Descriptions.

7.1.2 Position Title, Department, and Location: Provide the title, the department and the location of the position.

7.1.3 Primary purpose of role: Describe the primary purpose of the position in one or two brief sentences.

7.1.4 Essential functions: Most personnel perform a variety of duties. Describe the major, or most important functions and responsibilities of the position.

7.1.5 Tumour Biobank Responsibilities: Include all responsibilities that may be relevant for the position.

7.1.6 Qualification: Enter minimum education and/or certification required for the position.

7.1.7 Basic Competencies and minimum experience: Enter basic competencies and minimum work experience required.

7.1.8 Special Skills: List special skills required.
7.2 List of Roles and Responsibilities

7.2.1 ROLE: Information Technology Staff

RESPONSIBILITIES:

a. Conducts routine backup of database according to specific biobank plan.
b. Monitors Access to Informatics System.
c. Oversees data transmission – Schedules data export, monitors submission status, reviews process logs for errors and makes corrections when needed.
d. Monitors and implements security policy adopted by the biobank.
e. Uses best practices for computer hardware and software security.
f. Prepares and sends data records for external use.

7.2.2 ROLE: Clinical Research Coordinator/Nurse

RESPONSIBILITIES:

a. Obtains and Documents Consent.
b. Communicates with patients to inform them about the tumour biobank program.
c. Communicates with patients if consent is withdrawn.
d. Draws blood.
e. Public relations with clinical community. Interfaces with partners in clinical community.

7.2.3 ROLE: Data Entry Clerk

RESPONSIBILITIES:

a. Creates and maintains filing system for storing confidential records.
b. Retrieves records when needed.
c. Enter clinical and pathology data into database.
d. Enter consent information.
e. Enter inventory information if appropriate.

7.2.4 ROLE: Histology Technician/technologist

RESPONSIBILITIES:

a. Fixes tissue.
b. Embeds tissue in paraffin or Optimal Cutting Temperature Compound (OCT).
c. Cuts tissue sections.
d. Stains sections.
7.2.5 **ROLE:** Laboratory Technician/technologist  
**RESPONSIBILITIES:**  
a. Fixes tissue.  
b. Embeds tissue in paraffin or Optimal Cutting Temperature Compound (OCT).  
c. Cuts tissue sections.  
d. Prepares Tissue Microarrays.  
e. Freezes tissues and derivatives.  
f. Processes Tissue in derivatives such as DNA, RNA and protein.  
g. Processes and separates blood into components and derivatives.  
h. Assesses quality of tissues and derivatives.  
i. Contributes to development of technical SOPs.  
j. Labels and tracks samples.  
k. Records and documents laboratory processes.  
l. Enters inventory information into the database.  
m. Retrieves and ships samples according to procedure.

7.2.6 **ROLE:** Operating Room Nurse  
**RESPONSIBILITIES:**  
a. Communicates to Tumour biobank nurse that suitable sample may be available for biobanking.

7.2.7 **ROLE:** Pathology Coordinator/Assistant  
**RESPONSIBILITIES:**  
a. Primary lead on specimen collection.  
b. Harvests tissue.  
c. Processes tissue in pathology laboratory.  
d. Communicates to tumour biobank personnel that tissue is available for biobanking.  
e. Performs tasks assigned by the pathologist.  
f. Collects pathology reports about each case.

7.2.8 **ROLE:** Tumour Biobank Coordinator/Manager  
**RESPONSIBILITIES:**  
a. Contributes to the development of SOPs.  
b. Maintains SOPs for the biobank.  
c. Coordinates material requests and release.  
d. Coordinates development and maintenance of Informatics System.  
e. Investigates, reports and documents deviations in practice.
f. Coordinates quality assessment of samples.
g. Coordinates privacy and security is maintained in tumour biobank.
h. Coordinates training of tumour biobank personnel.
i. Coordinates Inventory verification.
j. Coordinates operations and Quality Assurance at Tumour Biobank.
k. Selects samples for shipment.

7.2.9 **ROLE:** Tumour Biobank Director/Head

**RESPONSIBILITIES:**

a. Oversees hiring of tumour biobank personnel.
b. Oversees education and training of tumour biobank personnel.
c. Responsible for approving SOPs.
d. Oversees material release.
e. Responsible for Operations at Tumour Biobank.

8.0 **APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES**

8.1 **Handbook for Good Clinical Research Practice.**

8.2 Responsibilities of Tumour Bank Personnel. OCRN SOP AD102.001 Draft version 3.

8.3 **Job Descriptions and Organizational Chart.** SOP HRS.001.00 British Columbia Tumour Tissue Repository.

8.4 Job Summaries, NCIC Clinical Trials Group, Kingston, Ontario.

9.0 **APPENDICES**

9.1 Appendix A – Job Description Form

10.0 **REVISION HISTORY**

<table>
<thead>
<tr>
<th>SOP Number</th>
<th>Date revised</th>
<th>Author</th>
<th>Summary of Revisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.102 e1.0</td>
<td>Aug 2008</td>
<td>JDSH</td>
<td>Initial release</td>
</tr>
</tbody>
</table>
| 1.1.102 e1.0 | Feb 2012 | CMG | • Grammatical and formatting updates throughout.  
• Removed the definition section  
• Revision History moved to bottom of document  
• Reference Links Updates  
• Updated SOP references.  
• Section 1: Deleted “The procedures apply to all roles at the tumour bank.”  
• Section 3: Inserted “Note that all CTRNet SOPs define roles and responsibilities.” |
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
</table>
|   | • Section 4: Deleted REB from the Tumour Bank Personnel list.  
• Section 7.2: Inserted opening sentence.  
• Section 7.2 (#3): Deleted “Files samples in freezer (storage)”. Inserted – enter consent information, and – enter inventory information if appropriate.  
• Section 7.2 (#5): Inserted “Enters inventory information into the database.  
• Section 7.2 (#8): Deleted #8, Physicians Associated with tumour bank program  
• Section 7.2 (#9): Deleted #9, Porter  
• Section 7.2 (#10): Deleted #10, Research Ethics Board Members |
Job Description Form

Position Title: 
Incumbent Name: 

Department: 

Location: 

Primary Purpose: 

Essential Functions: 

1. 

Responsibilities: 

Minimum Qualifications: 

Basic Competencies & Minimum Experience: 

Approved By ___________________________ Date ____________

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