1.0 PURPOSE

Tumour banks or repositories are intended to store and manage the Human Biological Materials (HBMs) in their custody. Appropriate storage is a core requirement for the operation of a successful tumour repository. On occasion this equipment may fail. Procedures must be in place to ensure that loss and damage to the collection is avoided.

2.0 SCOPE

This standard operating procedure (SOP) outlines processes that should be in place when freezers or refrigerators fail and samples must be transferred to back-up equipment.

3.0 REFERENCE TO OTHER POLICIES AND SOPS

1. CTRNet Policy: POL 007.001 Material and Information Handling Policy
2. CTRNet SOP: 4.1.006 Maintenance of Sample Storage Facility and Equipment

4.0 ROLES AND RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories that work at the repository site and are responsible for storing repository samples and/or transferring samples when storage equipment fails. This may include the following personnel:

<table>
<thead>
<tr>
<th>Tumour Bank Personnel</th>
<th>Responsibility/Role</th>
<th>Site Specific Personnel and Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Technicians</td>
<td>Responding to alarms, determining that equipment failure has occurred, transferring samples to back-up capacity</td>
<td></td>
</tr>
<tr>
<td>Bank Director, Bank Manager/Coordinator</td>
<td>Responding to alarms, overseeing or transferring material to back-up capacity, and updating lists and procedures</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Materials and Equipment</th>
<th>Materials and Equipment (Site Specific)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back-up storage capacity, freezers and refrigerators</td>
<td></td>
</tr>
<tr>
<td>Thermometers</td>
<td></td>
</tr>
<tr>
<td>Adequate Liquid Nitrogen, ice and dry ice supply</td>
<td></td>
</tr>
<tr>
<td>Insulated containers to temporarily hold dry ice and samples</td>
<td></td>
</tr>
<tr>
<td>Gloves and safety equipment to handle frozen boxes and samples</td>
<td></td>
</tr>
<tr>
<td>Alarm systems</td>
<td></td>
</tr>
<tr>
<td>Alarm system contact lists</td>
<td></td>
</tr>
<tr>
<td>Trolleys or carts to move samples rapidly</td>
<td></td>
</tr>
</tbody>
</table>
6.0 DEFINITIONS

**Human Biological Material:** All biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails, and substances extracted from such material such as DNA and RNA.

**Safety:** Processes, procedures and technologies to ensure freedom from danger or harm.

**Storage:** Maintenance of specimens for future use.

7.0 PROCEDURES

The storage facility (and storage equipment) is a key element in the operation of a tumour repository. In the case of freezer or refrigerator failure appropriate action should be taken to transfer the samples to back-up storage capacity with out damage to samples or loss of sample identity and tracking.

7.1 Back-up capacity

1. Provide adequate back-up capacity for low temperature units such as freezers and refrigerators in anticipation of equipment failure.

2. Have extra capacity, equal to at least the capacity of the largest storage unit, and equivalent to 10% (or other percentage as specified) of the total storage capacity, maintained at operating temperature at all times.

3. Identify and number back-up equipment.

7.2 Transfer initiation and Sample Transfer

1. Have trained personnel determine that equipment failure has occurred and that samples have to be transferred.

2. Make sure that adequate number of repository personnel are assigned to emergency response and trained to perform the transfer when required. Prominently post a 24-hour contact list for responsible personnel assigned to deal with an emergency situation (including in the evenings/nights or on weekends and holidays).

3. Train personnel in processes ensuring rapid transfer of HBMs to back-up units when the need arises.

4. Alert assigned personnel that a sample transfer has to be performed.

5. Avoid opening the failed freezer too often to avoid large temperature fluctuation to occur before transfer.
6. If back-up equipment is not situated close by, assemble carts or trolleys to aid in the transfer.

7. Fill insulated containers with dry ice or ice and place them on the carts.

8. Remove sample boxes from the freezers and place them on dry ice for transfer. Place sample boxes from refrigerators on ice for transfer. Essentially do not permit temperature fluctuations for extended periods of time.

9. Rapidly move samples to the back-up equipment.

10. If it is not possible to place samples in the same order as in the failed equipment make sure to maintain a logical or sequential pattern of storage.

11. Record details of back-up storage pattern.

12. Document sample transfer to back-up unit, and track samples to ensure return to correct location when corrective action has been taken.

13. Ensure that alarm systems are operational and monitored on back-up equipment as well.

8.0 APPlicable ReferEnces, REGuLatiOns aNd GUidELines


9.0 APPendices

None