<table>
<thead>
<tr>
<th>Name of Policy:</th>
<th>Tissue Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number:</td>
<td>3364-124-66</td>
</tr>
<tr>
<td>Department:</td>
<td>Nursing Service/Operating Room</td>
</tr>
<tr>
<td>Approving Officer:</td>
<td>Nurse Manager Operating Room</td>
</tr>
<tr>
<td>Responsible Agent:</td>
<td>Chief Nursing Officer/CNO</td>
</tr>
<tr>
<td>Scope:</td>
<td>Operating Room (OR)/Perioperative Services</td>
</tr>
</tbody>
</table>

**Effective Date:** 5/1/2016  
**Initial Effective Date:** July 11, 2007

(A) **Policy Statement**

The University of Toledo Medical Center (UTMC) ensures that donor tissue intended for transplantation or implantation use in procedures is appropriately acquired, received, stored, and issued in a controlled, systematic process to ensure the highest level of safety to each recipient.

(B) **Purpose of Policy**

To establish a process for the ordering, receiving, storing, and issuing of tissue in the OR.

(C) **Procedure**

1. **Oversight**
   a. The Nursing Manager of OR is the designated individual, responsible for oversight of tissue management, but may delegate responsibility for departmental compliance to the staff/service coordinators of the department.

2. **Source Facilities**
   a. Tissue banks issuing allografts to UTMC must be registered as a tissue bank with the Food & Drug Administration (FDA).
   b. Tissues received from Tissue banks and other source facilities must have met the required criteria set forth from the FDA.
   c. Verification of source facilities will be maintained by the Purchasing Department.

3. **Tissue Transportation**
   a. Containers for transportation must protect tissue from contamination and maintain tissue at appropriate temperatures during transport. Tissue should be placed in the appropriate storage as soon as possible after receiving tissue.
   b. Tissue must be stored in a secure area with access restricted to authorized personnel.

4. **Tissue Labeling**
   a. The tissue package should be labeled with the following information
      - Tissue ID number.
      - Description of tissue.
      - Name address and telephone number of tissue bank responsible for determining donor suitability, processing, storage, and distribution of the tissue.
5. Coordinating, Handling, and Storage of Incoming Tissue
   
a. Cryopreserved tissue
   - Cardiac/Vascular service coordinator or designee will coordinate incoming tissue.
   - Coordinator, in collaboration with Tissue Bank vendor and in-house purchasing personnel, will set
     up ordering of tissue and track arrival time to facility.
   - Upon Tissue arrival, the Surgical Support manager will be notified to complete the incoming tissue
     log.
   - Coordinator or designee will unpack tissue and ensure integrity of tissue packaging and will check
     that all paperwork is in order and appropriate temperatures were maintained during transport.
     Coordinator will secure tissue immediately to liquid nitrogen freezer.

b. Bone/Tissue – Ordering bone/tissue will be coordinated by the purchasing Department
   - Incoming bone/tissue will be coordinated by the Surgical Support staff.
   - Surgical Support staff will log in bone/tissue, check integrity of packaging and place in appropriate
     storage area (i.e., shelf in SSC or freezer).

6. Tracking and Record Keeping
   
a. The Tissue Inventory Log will be maintained in the following network folder; Common on
   ~utad.utoledo.edu/\Dfs$'(z:)
   Purchasing RMM Tissue Log, accessible to service coordinators, OR
   managers and designee. The following information will be logged in the allograft computer Log sheet:
   - Tissue Bank vendor
   - Tissue ID/Ref #
   - Lot #
   - Tissue Description
   - Exp Date
   - Date Implanted or Wasted
   - Patient ID number

b. Copy of original paperwork for veins and valves will be made and kept in CV/PV Service Coordinator
   office. Original paperwork for cryopreserved tissue will be kept in the filing cabinet at the OR front
   desk.

c. Instructions for thawing/preparing will be kept at the front desk filing cabinet.

d. Documentation of tissue will be placed on the OR record. The tissue ID # and description of tissue used
   will be included.

e. The OR staff will document any materials used to prepare or process tissues and any instructions used
   for preparation on the operating room record.

f. The source facility’s information card, or paperwork will be completed by the OR Circulator and placed
   in the Bone Bank mailbox.

g. All records will be kept for a minimum of ten years beyond the date of distribution, transplantation,
   disposition or expiration of tissue.
7. **Storage Guidelines**

a. Dehydrated musculoskeletal tissue should be stored at ambient temperature or cooler. Frozen musculoskeletal and osteoarticular tissue should be stored at −40° F (−40° C) or colder for long term storage. Cryo preserved cardiovascular tissue should be stored at −148° F or −100° C or colder. Tissue in refrigerator is stored at 33.8° F (1° C) to 50° F (10° C).

b. Autologus tissue should be segregated from allografts.

c. Tissue expiration should not exceed the following recommendations of the American Association of Tissue Banks (AATB).
   - Refrigerated musculoskeletal tissue: 5 Days
   - Refrigerated skin: 14 Days
   - Frozen and cryopreserved cells and tissue: 5 years
   - Lyophilized or dehydrated tissue: 5 Years.

d. The ultra low temperature (ULT) freezer and refrigerator temperatures will be checked and recorded daily on a temperature log by a Perioperative Tech.

e. The ULT and liquid nitrogen freezer are equipped with an alarm system that is continuously monitored and sounds when the temperature is not within acceptable range.

f. In the event of emergency power loss, manually check liquid nitrogen using measuring stick every hour. If level nears 4 inches, perform a manual fill. The freezer will have emergency back up power.

g. Tissue stored at ambient temperature will have the temperature checked and recorded daily on a temperature log kept by the Surgical Support staff or Perioperative Tech in the OR.


9. **Tissue Recall**

a. In the event that the FDA or issuing facility initiatives a product recall, the operating room will determine if the recall is applicable to the organization.

b. If any patient has received the tissue recalled, Risk Management will be notified for investigation and follow up.

c. If any product is in the institution, it will be removed from storage immediately.

### Approved by:

<table>
<thead>
<tr>
<th>C. Powel, BSN, RN</th>
<th>5-23-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christina Powlesland, BSN, RN. Nurse Manager Operating Room</td>
<td>Date</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moneega Smith, MSN, RN</th>
<th>5-23-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moneega Smith, MSN, RN. Chief Nursing Officer/CNO</td>
<td>Date</td>
</tr>
</tbody>
</table>

**Review/Revision Date:**
- 11/10/2008
- 12/3/2008
- 10/28/11
- 5.1.2016

**Next Review Date:** 5/2019

*It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.*

Policies Superseded by This Policy: 4-66