Institutional Handbook of Operating Procedures Policy 09.13.42	
Section: Clinical Policies	Responsible Vice President: Senior Vice President, Chief Medical & Clinical Innovation Officer
Subject: General Procedures and Care	Responsible Entity: Hospital Administration

I. Title

Tissue and Bone Procurement, Storage, and Distribution

II. Policy

This policy is to provide a human cell, tissue, and cellular and tissue -based products management program and to outline requirements for safe acquisition, receipt, storage, distribution, and tracking, per regulatory requirements. This policy also defines the management process regarding audits, recalls, and investigation of adverse events or infectious complications related to tissue(s). This policy applies to all UTMB facilities.

III. Procedures

A. Acquisition and Receipt

1. All tissue(s) ordered by an UTMB facility will be tracked by a reference identification and serial number or unique tracking identification number and entered into UDITracker® OR (UDI) and paper tracking log.

2. Supply Chain, Perioperative Services Coordinator, or practice manager/nurse supervisor places orders for tissue/bone with the operating room (O.R.) Senior Supply Administrator or Ambulatory purchasing, who then places the order directly with the company or supplier via purchase order.

3. Designated Perioperative Services Administration staff or Ambulatory requesting department's supervisor/manager validates the designated company's licenses and registration with the appropriate authorities annually (state, and federal).
    a. FDA Registration: Verification of a sources facility's registration with the FDA is performed on new vendors and annually thereafter.

4. The designated company transports the tissue/bone to UTMB according to manufacturer guidelines. Tissue must be transported, handled, and stored according to the source facility's or manufacturer's directions.

5. Designated Perioperative Services Administration staff or assigned clinical staff receive the tissue/bone and verifies package integrity and ensures storage-related temperature parameters have been maintained.

6. Designated Perioperative Services Administration staff or assigned clinical staff records receipt of the tissue/bone, lot number and expiration date into a paper tracking log and UDI database.

7. Designated Perioperative Services Administration staff or assigned clinical staff immediately notifies Service Coordinator or provider of the arrival of the tissue/bone, if necessary.
8. Documentation
    a. All tissue, once received, must be recorded in the UDITracker® and for clinics, on a paper tracking log (See Human Tissue Log)
    b. All tissue, once implanted, must be appropriately documented in EPIC
    c. The patient implant card must be sent back to the manufacturer and a copy will be kept with the paper tissue tracking form (clinics) or with the intraoperative record.
    d. UDI database must be maintained on receipt and use or disposition of tissue

B. **Compromised Tissue** – Tissue must not be used if any of the following conditions exist:
    a. The container seal is damaged or otherwise not intact
    b. The container is physically damaged
    c. Storage and transport did not meet manufacturer's specifications

C. Storage of tissues

1. Service Coordinator or assigned clinical staff places the tissue/bone in the appropriate storage area/device as recommended per manufacturer guidelines.

2. Service Coordinator or assigned clinical staff records the receipt of the incoming tissue/bone into a paper tracking logbook maintained especially for that service and records receipt in UDI database.

3. Daily monitoring and recording of all tissue/bone storage devices (in terms of temperature maintenance and gross functional integrity) is carried out by trained OR staff, facilities department or clinical staff.
    a. Tissues stored in 'ambient air' (room temperature) such as freeze-dried bone, require monitoring of the air temperature once daily, with records of that reading maintained.

4. Routine periodic maintenance is performed on tissue/bone storage equipment by UTMB Clinical Equipment Services in order to ensure functional integrity of the equipment as well as proper functioning of alarms and back-up systems. In the event of hospital evacuation (i.e. natural disasters, extended electrical power failure, interruption in monitoring), all refrigerated and frozen tissue and bone will be discarded and recorded as such by the service coordinators or clinical staff. Ambient temperature tissue/bone will be sent to a predetermined emergency storage location along with ambient medications. Temperature will be recorded during transport and handling with an approved temperature monitoring device.

5. Service Coordinators or assigned clinical staff perform periodic inventory on stored tissue/bone in order to monitor tissue/bone availability as well as expiration dates.

6. Expired tissue/bone is either returned or discarded according to recommended manufacturer guidelines.

7. Expired or discarded tissue/bone is recorded into the UDI database and the paper tracking log.

D. Distribution of Tissue

1. A registered nurse (RN) or assigned clinical staff obtains appropriate surgical tissue/bone as ordered by the surgeon/provider.

2. RN or assigned clinical staff verifies storage parameters and package integrity have been maintained and checks the expiration date of the tissue/bone.

3. RN, provider, or assigned clinical staff follows manufacturer guidelines when opening and/or preparing tissue/bone for use on the surgical field.

4. RN or assigned clinical staff documents the use of the specific surgical tissue/bone, surgical site of tissue/bone implantation, manufacturer lot number, the tissue expiration date, and all other necessary information in the patient's intraoperative record in EPIC.

E. Adverse Events

1. Adverse events related to the distribution of tissue/bone to a recipient will be investigated. Tracking information from all records and logbooks including, but not limited to, tissue/bone description, numeric lot/serial information, shipping and expiration dates, source facility, etc. will be accessed and documented.
2. The adverse event should be entered into the UTMB incident reporting software tool in accordance with the Unusual Event Reporting Policy within 24 hours by the person who is involved in, observed, or discovered the event. Risk Management and/or Quality Management will be notified as appropriate. Additionally, as soon as UTMB is aware of an adverse event related to the use of tissue, the event will be reported to the tissue supplier.

IV. Definitions

Tissue – Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen.

UDI- UDITracker® OR is a software that simplifies the critical task of regulatory compliance, recall investigation, and managing expiring inventory, by tracking and managing all implants, including tissue, orthopedic, cardiovascular and all other implants.

V. Relevant Federal and State Statutes or Guidelines

The Joint Commission Standard TS.03.01.01

VI. Related UTMB Policies and Procedures

Human Tissue/Bone Transplant Tracking Log
Human Tissue Log
Unusual Event Reporting

VII. Dates Approved or Amended

Originated: 08/15/2018	
Reviewed with Changes	*Reviewed without Changes*
04/04/25	
08/27/25	

VIII. Contact Information

Perioperative Administration (409) 266-7866