LAC+USC MEDICAL CENTER POLICY

Subject:	Original Issue Date:	Policy #
TISSUE TRANSPLANTATION	8/30/09	**232.1**
	Supersedes: 11/8/16	Effective Date: 3/27/20

Departments Consulted:	Reviewed & Approved by:	Approved by:
Laboratory and Pathology Perioperative Services Health Information Management Product Standardization Committee Neonatology Tissue and Organ Committee	Attending Staff Association Executive Committee Senior Executive Council	(Signature on File) Chief Medical Officer (Signature on File) Chief Executive Officer

PURPOSE

To provide guidance for the management of human or human-derived tissue for use in patient care.

POLICY

To ensure the safe utilization of human and human-derived tissue, including its acquisition, storage, and dispensing, and ensure proper documentation and management of its use, the Department of Laboratories and Pathology's Blood Bank manages a Tissue Dispensing Service (TDS). The storage and issuance of human and human-derived tissue will be centralized within the Blood Bank (D&T Building, Room 2D422) with the exception of human breast milk. Human breast milk falls under the tissue license of the Neonatology Service and is managed and stored by them. Non-human derived materials used for transplantation do not fall under the scope or operating license of either the TDS or the Neonatology Service.

The TDS and Neonatology Service will only obtain tissue from qualified vendors who comply with State of California and FDA rules, regulations, and guidance, when applicable.
All vendors must test human-derived tissue donors for Syphilis, HIV-1, HIV-2, HTLV-I, HTLV-II, Hepatitis B, and Hepatitis C. Only human and human-derived tissue from donors who have been tested and found to be non-reactive will be grafted. Although human and human-derived tissue will be purchased by and stored under the oversight of the TDS or Neonatology Service, only human and human-derived tissues that have been approved by the Value Analysis Director after first being approved by the Tissue Dispensing Service or Neonatology Service will be utilized.

Records shall be maintained as required by applicable Federal and State laws, rules and regulations and accrediting agency requirements.

The remainder of this policy pertains only to those human tissues that fall under the purview of the Tissue Dispensing Service.

DEFINITIONS

Tissue: Any human cell, group of cells, tissue or organ including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, blood, other fluids and any other portion of a human body (State of California Health and Safety Code Section 1635).

Transplantation: The act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being.

TISSUE MANAGEMENT PROCESS

- There shall be an unbroken chain of transfer for tracking human and human-derived tissue products from the time of receipt by the TDS until use for patient care or other disposition.
- Human and human-derived tissue issued for a specific patient shall not be utilized for the care of any other patient.
- Manufacturer's guidelines, i.e., product insert, must be followed in preparation and processing of all tissue products.

PROCEDURE

Prior to adding any new tissue to the formulary, the proposed product must be vetted by the Tissue Dispensing Service. Upon approval by the TDS, the request for new human tissue product must also be approved by the Director of Value Analysis.

Request and Purchase

- All human or human\-derived tissue products used for patient care within the Medical Center must be purchased by and shipped directly to the TDS (except where exceptions have been previously authorized).

- The TDS shall maintain a list of approved human and human-derived tissue products and vendors. Approval is made by the Director of the TDS and the Director of Value Analysis.

- Requests for human or human-derived tissue products must be made on Tissue Dispensing Service (TDS)/Blood Bank Request and Record, Form 837, and must include the following information:

Patient's name, MRN, patient unit, diagnosis and/or reason for the request, the human or human-derived tissue being requested, date of request, quantity and/or size/surface area requested, surgery date, patient unit telephone extension, and the requesting physician's name, ID#, and pager number.

- The TDS shall maintain an inventory stock of the most commonly used human and human-derived tissue products and shall provide a list of these products to physicians upon request.

- Requests for on-formulary, stocked human or human-derived tissue products must be submitted to the TDS one day prior to the scheduled surgery date.

- Requests for on-formulary but non-stocked human or human-derived tissue products must be submitted to the TDS at least five (5) business days prior to the scheduled surgery date (sooner if the surgery date is known) and must be approved by an Attending Physician from the requesting department.

- Requests for off-formulary human or human-derived tissue products must be submitted to the TDS at least two weeks prior to the scheduled surgery date. (The TDS is authorized to purchase off-formulary human or human-derived tissue products on a one-time basis only until the product has undergone the approval process.

- Requests for emergency purchase of off-formulary human or human-derived tissue products must be approved by the Medical Director of the Operating Rooms before the request is submitted to the Tissue Dispensing Service. In the event the Medical Director of the OR is not available, the Director of the Tissue Dispensing Service has jurisdiction.

Receipt and Storage

- The TDS shall store all human and human -derived tissue products following vendor instructions (except where authority has been delegated by the TDS).

- The TDS shall visually inspect and document receipt of all human and human-derived tissue products, rejecting and notifying the vendor of all compromised packaging or improper shipping conditions.

- Human or human-derived tissue products will be issued by the TDS upon presentation of a *Blood/Tissue Call Card* (Form 419), signed by two licensed personnel (MD, RN, PA, LVN, NP), certifying that they have verified the physician's order and the patient's identification.

Documentation

- At the time the human or human-derived tissue product is transplanted, the white copy of *Tissue Dispensing Service (TDS)/Blood Bank Request and Record,* Form 837 shall be completed and placed in the patient's medical record.

- The yellow copy of the completed TDS Form 837 shall be returned to the TDS to document tissue disposition.

- Unopened, unused tissue products shall be returned to the TDS, along with Form 837, dated and signed, certifying that the returned tissue/tissue product has been properly stored as directed by the vendor while outside the control of the TDS. This requirement is met by the signature of the attending physician, operating surgeon or a surgical room RN.

- Opened but unused tissue shall be disposed of in the operating room, documenting on Form 837 that the tissue was discarded.

- Tissue transport containers shall be returned to the TDS upon completion of the case.

The completed, signed and dated manufacturer's tissue tracking card shall be returned to the TDS upon completion of the case. This includes unused tissues discarded in the operating room. The TDS is responsible for returning these cards to the vendors.

ADVERSE EVENTS

All side effects, acute reactions and short- and long-term complications must be reported to the TDS Medical Director as soon as possible after discovery of the reaction/complication. Examples: Anaphylaxis, suspected graft-related bacterial or viral infection/sepsis, long-term complications such as graft-associated viral hepatitis, HIV, and Creutzfeld-Jacob Disease. Recipient notification, as well as notification of the tissue source agency and regulatory agencies, may be indicated and must be documented. If any reaction related to tissue transplantation occurs, the Medical Director of the Tissue Dispensing Service (or designee) must be notified immediately. Referral to Tissue and Organ Committee for any adverse events.

RESPONSIBILITY

Neonatology Service
Physicians
Tissue Dispensing Service
Perioperative Services Nursing
Supply Chain Operations (Product Standardization Committee)

PROCEDURE DOCUMENTATION

Neonatology Service
Physicians
Tissue Dispensing Service
Perioperative Services Nursing

REFERENCES

State of California Health and Safety Code Section 1635 through 1648.
42 CFR, Part 486.
CMS Conditions of Participation, A-0884, A-0885, A-0886, A-0887, A-0888, A-0889, A-0890, A-0891, A-0892.
Joint Commission Chapter on Transplant Safety, Standard TS. 01.01.01, TS. 02-01-01, TS. 03-01.01, TS 03.02.01.

REVISION DATES

July 9, 2013; November 8, 2016, March 27, 2020