

Beaumont

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 Applicability FH, GP, RO, Troy

Tissue General Information

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the Transfusion Medicine staff with an overview of the tissue dispensing service and to define expected responsibilities associated with the service.

II. CLINICAL SIGNIFICANCE:

Transfusion Medicine at Corewell Health East's Farmington Hills, Grosse Pointe, Troy and Royal Oak campus' have an expanded role to also manage biologic and human tissue products for the purpose of transplantation. The responsibilities of ordering, receiving, storing, and issuing tissue are centrally located within the hospital's Transfusion Medicine Service and are available for transplantation upon physician's request.

III. DEFINITIONS/ACRONYMS:

- A. **Tissue:** Any group of human functional cells and/or intercellular matrix intended for implantation, transplantation, or other therapy.
- B. **Osteoarticular Allograft:** A tissue graft that contains both bone, tendon, and/or muscle; always a special order
- C. **Osteochondral Allograft:** Tissue graft containing both bone and cartilage; often contains living cartilage cells and is received as a fresh graft
- D. **Tissue Distribution Intermediary:** An intermediary agent who acquires and stores cells/tissue for further distribution and performs no other tissue banking function.
- E. **Tissue Dispensing Service:** Any entity that receives, stores, and provides cells/tissue directly to the end-user for immediate transplantation. Tissue dispensing services may or may not be

tissue banks, depending on what other functions they perform.

- F. **Tissue Bank:** An entity that provides or engages in one or more services involving cells/tissue from living or deceased individuals for transplantation purposes. These services include assessing donor suitability, recovery, processing, storage, labeling, and distribution of cells/tissue.
- G. **End-User:** A health care practitioner who performs transplantation procedures.
- H. **IS:** An abbreviation used to refer to a computer information system.
- I. **CAP:** College of American Pathologists
- J. **AABB:** Association for the Advancement of Blood & Biotherapies

IV. GENERAL POLICY:

Define	Policy	Notes
Role of Transfusion Medicine	<ol style="list-style-type: none"> 1. Orders, receives, stores, and issues tissues for the purpose of traceability and trackability. 2. Promotes tissue management standards as described by CAP, AABB, and the Joint Commission are met or exceeded the minimal of these regulatory bodies. 3. Monitors inventory for waste and usage and reports to various committees as directed by administration. 	<ol style="list-style-type: none"> A. The tissue dispensing service is not a distribution intermediary. B. Tissues are received directly from the supplier and remain on campus until final transplantation into the recipient, discard, or return to the supplier.
Hours of Operation	<ol style="list-style-type: none"> 1. The tissue dispensing service is available to the end-user 24 hours/7 days a week, including holidays. 	
Maintenance of Tissue Inventory	<ol style="list-style-type: none"> 1. The tissue dispensing service will maintain par levels of defined tissues as directed by the end-users. 	<ol style="list-style-type: none"> A. Changes in form, variety, and manufacturer of a particular tissue must be reviewed and approved by the Value Analysis Team (VAT) associated with the tissue's end-users group. <p>For example: A change in a tissue bank for particular tendon must be evaluated by the</p>

		Sports Medicine VAT.
Special Requests for Tissue	<ol style="list-style-type: none"> 1. The tissue dispensing service will make every effort to fill requests for tissue not maintained in the general inventory if the following criteria are met: <ol style="list-style-type: none"> a. A written order from the end-user is received for the tissue b. The order is received 36 hours prior to need c. Patient name, birth date, and end-user are defined 	<ol style="list-style-type: none"> A. Human tissue is donor dependent and not always available. B. Delivery of tissue is dependent on factors of weather, supplier availability, and transportation.
Compliance	<ol style="list-style-type: none"> 1. The tissue dispensing service will comply with all standards and guidelines set forth by the following: <ol style="list-style-type: none"> a. Internal: <ol style="list-style-type: none"> i. Blood Transfusion – Tissue Committee ii. Blood Bank Medical Director b. External: <ol style="list-style-type: none"> i. AABB ii. College of American Pathologists iii. The Joint Commission 	
	<ol style="list-style-type: none"> 1. Personnel consist of the following: <ol style="list-style-type: none"> a. Blood Bank Medical Director <ol style="list-style-type: none"> i. Oversees all aspects of the tissue dispensing 	

<p>Personnel Responsibility</p>	<p>service.</p> <p>b. Blood Bank Manager/ Supervisor</p> <ul style="list-style-type: none"> i. Approves the design and function of the tissue dispensing service. ii. Acknowledges content and text of various documents contained within the tissue dispensing service. <p>c. Hospital Tissue Coordinator</p> <ul style="list-style-type: none"> i. Supports the function and design of the tissue dispensing service. ii. Monitors compliance with current regulatory and accreditation standards. iii. Monitors implementation and the appropriateness of changes. iv. Liaison to hospital staff inside and outside of the Blood Bank regarding all 	
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	<p>tissue product matters.</p> <p>v. Responsible for the safety and efficacy of human tissue products on the Royal Oak, Farmington Hills, Grosse Pointe, and Troy campuses.</p> <p>d. Tissue Management Medical Technologist</p> <p>a. Supports the function and design of the tissue dispensing service.</p> <p>b. Monitors implementation and the appropriateness of changes.</p> <p>c. Liaison to hospital staff inside and outside of the Blood Bank regarding all tissue product matters.</p> <p>e. Tissue Service Clerk</p> <p>i. Performs the following duties under the direction of the Tissue Coordinator:</p> <p>ii. Orders tissue.</p> <p>iii. Prepares billing.</p> <p>iv. Confirms</p>	
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	<p>product orders.</p> <p>v. Maintains tissue orders, physician request, and dispensing records.</p> <p>f. Medical Technologist in Blood Bank</p> <p>i. Receives, stores, issues, and returns tissue products to inventory.</p>	
Internal Compliance	<p>1. The tissue dispensing service complies with all policies and procedures set forth in the:</p> <p>a. Blood Bank Quality System Documents</p> <p>b. Corewell Health Safety Documents</p> <p>c. Clinical Pathology Procedure Documents</p>	

V. OPERATIONAL GUIDELINES:

Operation	Guideline	Notes
Discard of Tissue	Discarded, wasted, or any tissue that is deemed unsuitable for transplantation must be handled as controlled biohazard waste.	See Transfusion Medicine policy, Quarantining and Discarding Tissue .
Tissue Supplier Qualification	Qualifying suppliers for transplantable human tissue is accomplished using the process set forth in the Blood Bank Quality System Documents.	See tissue package inserts: See Tissue Supplier Qualification and Reference Manual
Transfer of Tissue	Transfer of tissue to another hospital campus is strictly prohibited and can only be executed with medical director approval.	See Transfusion Medicine policy, <i>Emergency Request and Transfer of Tissue</i> .
Tissue Dispensing	Process control is accomplished using the process set forth in the Blood Bank	See Transfusion Medicine policy, Issue of Tissue Products and Return of Tissue

Processes	Quality System Documents.	<i>Products Back into Inventory.</i>
Tissue Dispensing Records Management	Tissue dispensing records are maintained and controlled adhering to the policies set forth in the Blood Bank Quality System Documents and the Transfusion Medicine Procedure Documents.	See Transfusion Medicine policy, <i>Blood Bank Records.</i>
Storage Equipment Operations	The walk-in refrigerator, freezers, liquid nitrogen tank used for tissue storage are continuously monitored, maintained, and calibrated in accordance with the Blood Bank Quality System Documents and the Transfusion Medicine Procedure Documents.	See Transfusion Medicine policy series – Quality Assurance.

VI. REFERENCES:

1. AABB, Standards for Blood Banks and Transfusion Services, current edition.
2. American Association of Tissue Banks, Standards, current edition
3. Tissue package inserts: See Tissue Supplier Qualification and Reference Manual

Approval Signatures

Step Description	Approver	Date
Policy and Forms Steering Committee (if needed)	Kristina Davis: Staff Physician	10/26/2023
	Ryan Johnson: OUWB Clinical Faculty	10/24/2023
	Vaishali Pansare: Chief, Pathology	10/23/2023
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	Kelly Sartor: Mgr, Division Laboratory	10/10/2023
	Abigail Swaney: Medical Technologist Lead	10/10/2023
	Karrie Torgerson: Supv, Laboratory	10/9/2023

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10/6/2023

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