

Beaumont

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Area **Laboratory-Blood**
Bank

Applicability **FH, GP, RO, Troy**

Emergency Request And Transfer Of Tissue

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide Transfusion Services with specific guidelines for responding to emergent requests for tissue from other facilities.

II. CLINICAL SIGNIFICANCE:

Tissue available for transplantation at Corewell Health Farmington Hills, Grosse Pointe, Royal Oak, and Troy may not be distributed to any other facility. Tissues that are received and stored at a facility must remain at their site unless there is indication to return the tissue back to the source tissue bank or tissue intermediary. Distributing tissue to other facilities, including other Corewell Health campuses, is a manufacturing process that requires adherence to CFR 1271 and registration as a Tissue Establishment with the FDA.

III. DEFINITIONS:

Tissue Distribution Intermediary: An intermediary agent who acquires and stores cells and/or tissue for further distribution and performs no other tissue banking process.

Tissue Establishment: Establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation.

IV. GENERAL POLICY:

Transferring or lending tissue to another facility is strictly prohibited. Emergent request for such activity by another health care facility must be carefully evaluated and approved by the Transfusion

Medicine Director or designee, and requires FDA notification.

Borrowing or transferring tissue from another facility into Corewell Health Farmington Hills, Grosse Pointe, Royal Oak, or Troy, may occur if the outside facility is registered with the FDA as a Tissue Establishment.

V. PROCEDURE:

Step	Action	Notes
1.	<div>Notify the appropriate individuals of the emergent request:<ul style="list-style-type: none">• Transfusion Medicine Director• Hospital Tissue Coordinator and/or designee</div>	
2.	Document the request to transfer or lend tissue on an online variance form. Refer to Variance Reporting for details	Include the following on an online variance. (Refer to Variance Reporting for details). <ul style="list-style-type: none">• name of the health care facility• address• contact name• contact phone number• type of tissue needed and quantity• explanation of the urgent request
3.	Inform the requester that your site is not registered with the FDA as a Tissue Establishment for this tissue banking activity.	The completion of a tissue product transfer to another healthcare facility needs to be done under the knowledge and consent of the Transfusion Medicine Director, Hospital Tissue Coordinator and/ or designee.
4.	Seek written permission of the transfer from the Transfusion Medical Director or designee.	Print a copy of the variance for signature documentation.
5.	<div>A. Send requested tissue if permission is granted.<ul style="list-style-type: none">1. Package tissue in accordance with the tissue's temperature storage specifications.2. Transfer tissue in the Transfusion Medicine Information System.</div>	<ul style="list-style-type: none">• Storage temperature and integrity must be maintained during transfer of tissue.• Transportation should be arranged by the requester.• Once tissue is sent, the requesting hospital may not send the tissue back.

	B. If the request is denied, inform the requester.	
6.	E-mail the Hospital Tissue Coordinator a copy of the variance with authorizing signature.	This step will alert the Tissue Coordinator of the event so that necessary follow-up for compensation and FDA registration can occur.

VI. WARNINGS:

The FDA considers the transferring or lending tissue a manufacturing process and would require your Corewell Health facility to register using Form FDA 3356 as a Tissue Establishment within 3 days of performing this activity.

Refer to FDA link: <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm>

VII. REFERENCES:

- American Association of Blood Banks, *Standards*, current edition
- American Association of Tissue Banks, *Standards*, current edition

Approval Signatures

Step Description	Approver	Date
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Applicability

Farmington Hills, Grosse Pointe, Royal Oak, Troy

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