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Document Contact	Wendy Frizzo: Bone and Tissue Coordinator
Area	Laboratory-Blood Bank
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Emergency Storage of Tissue

Document Type: Procedure

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I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide Transfusion Services staff with specific guidelines for moving tissue products to an alternative location when the current storage area becomes compromised. Compliance to these guidelines will promote the quality of the tissue provided by Transfusion Services.

II. CLINICAL SIGNIFICANCE:

Many tissue products are stored in controlled temperatures to ensure the viability and integrity of the tissue. These storage units may become compromised in internal disasters such as power failures, storm damage, equipment failure, flood, etc. Incidences such as these may require tissue products to be moved from the current storage area to another temporary location on-site or off-site of the hospital. Management will determine when it is necessary to move tissue from one location to another. At the time it is deemed necessary to relocate tissue, document the decision on an on-line variance. Refer to Transfusion Medicine policy, *Variance Reporting*, for details.

III. PROCEDURE:

The tables below include direction for tissue storage alternatives and relocating tissues to appropriate alternative storage areas once the current location is deemed unstable:

A. Emergency Tissue Storage Alternatives:

Current Location	Move To

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Room Temperature	A. Long term storage: 1. Royal Oak: a. Transfusion Services at Grosse Pointe: (313) 473-1949 2. Troy, Farmington Hills, and Grosse Pointe: a. Transfusion Services at Royal Oak: (248) 898-9010 B. Temporary Storage: 1. Royal Oak: a. Transfusion Services Lead Technologist office b. Any alternate location designated by the acting supervisor that is free of water and extreme temperature and is temperature monitored. 2. Troy, Farmington Hills, and Grosse Pointe: a. Any alternate location designated by the acting supervisor that is free of water and extreme temperature and is temperature monitored.
Ultra Low Freezer	A. Long term storage: 1. Long term storage must be continuously monitored for temperature and monitoring records must be retrievable. Refer to Transfusion Medicine policy, *Manual Temperature Monitor*. a. Royal Oak: i. Transfusion Services at Grosse Pointe: (313) 473-1949 b. Troy, Farmington Hills, and Grosse Pointe: i. Transfusion Services at Royal Oak (248) 898-9010 B. Temporary Storage: 1. Royal Oak: a. Styrofoam™ Frozen Tissue Coolers temporarily stored in the Transfusion Services Information Systems office or any alternate location designated by the acting supervisor that is free of water and extreme temperature.: b. Ultra-low freezer #1, #2, #4, #5, #8, and #23. i. When moving tissue to an Ultra-low freezer; ensure that the temperature is colder than -65 °C.

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	2. Troy: a. Freezer 1 or Freezer 2 (if Freezer 1 is unavailable) 3. Farmington Hills: a. AP Ultra-low freezer b. Tissue Freezer H 4. Grosse Pointe: a. Ultra-Low Chest Backup Tissue Freezer b. Styrofoam™ Frozen Tissue Cooler stored in any alternate location designated by acting supervisor that is free of water and extreme temperature
Liquid Nitrogen	A. The 2300 LN^2 storage unit is set to alarm when the level of liquid nitrogen drops below 12 inches. The storage unit loses approximately 5 inches per day. Should the storage unit need to be moved and/or detached from its power supply and/or liquid nitrogen supply tank, the tissue should remain in the storage unit and transported. 1. Long term storage: a. Royal Oak: i. Anatomic Pathology at Grosse Pointe: (313) 473-1949 b. Troy, Farmington Hills, and Grosse Pointe: N/A 2. Temporary storage: a. Royal Oak: i. Liquid Nitrogen O.R. Transport Dewar ii. This Dewar will be temporarily stored in the Transfusion Services Lead Technologist office or any alternate location designated by the acting supervisor that is free of water and extreme temperature. b. Troy, Farmington Hills, and Grosse Pointe: N/A
	A. Long term storage: 1. Royal Oak: a. Transfusion Services at Grosse Pointe: (313) 473-1949 b. Michigan Eye Bank i. Cornea tissue should be sent back

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Refrigeration	immediately to the eye bank if the patient's surgery is postponed or canceled due to the emergency. ii. Eversight Eye Bank: (800) 247-7250 2. Troy: N/A 3. Farmington Hills: a. Refigerators A, B, C, D 4. Grosse Pointe: a. Transfusion Services at Royal Oak (248) 898-9010 B. Temporary storage: 1. Royal Oak: a. Designated Igloo® Human Tissue Cooler with wet ice temporarily stored in the Transfusion Services Lead Technologist office or any alternate location designated by the acting supervisor that is free of water and extreme temperature. 2. Troy: N/A 3. Farmington Hills: a. Refrigerators A, B, C, D 4. Grosse Pointe: a. Helmer Blood Bank Refrigerator #2 b. Chemistry Refrigerators C. Coolers containing wet ice must be monitored every 4 hours. Refer to Transfusion Medicine policy, *Manual Temperature Monitor*

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B. Emergency Tissue Storage Relocation:

Action	Notes
Remove tissue from the compromised location and pack in the appropriate temporary storage container (if necessary), and move tissue to the appropriate alternative long term storage area stated in the above table.	A. Proper temporary storage and transport for long term: 1. Frozen tissue may be temporarily stored on dry ice for 24 hours. After 24 hours, frozen tissue must be moved to long term storage. 2. Tissue stored in liquid nitrogen must be stored in a

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	fully charged O.R. Transport Dewar. 3. Refrigerated tissue must be stored on wet ice and the thermometer reading must range between 2-8°C. 4. Coolers containing wet ice must be monitored every 4 hours. Refer to Transfusion Medicine policy, *Manual Temperature Monitor* and Blood Bank form, *Manual Temperature Monitor*.
Record the following on an on-line variance. Refer to Transfusion Medicine policy, *Variance Reporting*. A. Date, time, and person responsible for authorizing the relocation. B. Affected location or storage unit and the new relocation area. C. Cause of relocation.	A. For equipment failure of a single ultra-low freezer, refer to Transfusion Medicine policy, *Response to an Alarm Condition,* and Blood Bank form, *Temperature Alarm Activation Log*.
Off-Site Transfer of Tissue: A. Transfer the effected tissue inventory in Transfusion Service IS using Blood Bank CDM, *Transfer Units,* and print 2 copies of the transfer list: 1. 1 copy is retained for the variance. 2. 1 copy should accompany the transfer. B. On-Site Relocation: 1. See next action.	A. If the Transfusion Service IS is not available or functional, a downtime record of the involved inventory must be documented on Blood Bank form, *Downtime Emergency Tissue Transfer Form*. If time does not permit, this may occur at the relocation site. Include: 1. Tissue description 2. Expiration date 3. Unique identifier B. The long term alternative storage site must receive the tissue into inventory. This ensures historical traceability.
On-Site Relocation: A. Monitor and record the temperature of any ***temporary*** storage device using Blood Bank form, *Manual Temperature*	A. Record the addition of coolant and interval temperature readings once the temporary storage device exceeds its validated time allotment.

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Monitor.	B. Refer to Transfusion Medicine policy, *Manual Temperature Monitor* and Blood Bank form, *Manual Temperature Monitor.*
Return of Tissue to Original Storage Location: A. Document the following on the initial on-line variance. Refer to Transfusion Medicine policy, *Variance Reporting,* when the tissue is returned to its original location. B. Date, time, and the person responsible for authorizing the return of tissue to the original storage area or unit. C. Current location/storage unit and the original location/storage unit. D. Attach a copy of the returned inventory. E. Attach a copy of any return to service/ maintenance documentation.	A. Tissue being transferred back to the original site must be entered into the Transfusion Service IS using Blood Bank CDM, *Transfer Units,* and print the transfer list. This ensures historical traceability.
Receive tissue back into the Transfusion Medicine IS.	A. Refer to Blood Bank CDM, *Delivery of Previously Returned Tissue Products.*
Place the tissue in the appropriate storage location/unit.	A. Place unsatisfactory or questionable tissues in the appropriate quarantine areas. Refer to Transfusion Medicine policy, *Tissue Quarantine Policy.*

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IV. SPECIAL NOTES:

A. The FDA considers the transferring or lending tissue a manufacturing process and would require the blood bank to register using Form FDA 3356 as a Tissue Establishment within 3 days of performing this activity. Although this may be an emergent situation, transferring tissue to an emergency storage location off campus may require registration with the FDA. Consult the Blood Bank Medical Director. Applicable to all sites.

1. FDA Tissue Establishment Registration Form

V. REFERENCES:

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

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Attachments

F-906, Downtime Emergency Tissue Transfer Form.pdf

Approval Signatures

Step Description	Approver	Date
	Kristina Davis: Staff Physician	1/24/2024
	Vaishali Pansare: Chief, Pathology	1/4/2024
	Ryan Johnson: OUWB Clinical Faculty	1/3/2024
	John Pui: Chief, Pathology	1/2/2024
Policy and Forms Steering Committe (if needed)	Wendy Frizzo: Bone and Tissue Coordinator	1/2/2024
	Abigail Swaney: Medical Technologist Lead	12/1/2023
	Karrie Torgerson: Supv, Laboratory	12/1/2023
	Kelly Sartor: Mgr, Division Laboratory	11/29/2023
	Teresa Lovins: Supv, Laboratory	11/28/2023
	Wendy Frizzo: Bone and Tissue Coordinator	11/28/2023

Applicability

Farmington Hills, Grosse Pointe, Royal Oak, Troy

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