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Document Contact	Wendy Frizzo: Bone and Tissue Coordinator
Area	Laboratory-Blood Bank
Applicability	Farmington Hills, Royal Oak, Troy

Tissue Complication/Adverse Reaction Policy

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the Transfusion Medicine with specific guidelines for documenting and responding to reports of adverse outcomes, suspected disease transmission, or graft failure subsequent to tissue transplantation.

Reported or suspected adverse outcomes, including transmitted diseases or other complications potentially related to tissue transplantation, shall be evaluated by the Director of the Transfusion Medicine. When deemed necessary by the medical director, these reports shall be communicated to the supplier in a timely fashion and in accordance with applicable federal regulations / guidelines and reported to the tissue supplier if a problem potentially related to the graft develops subsequent to transplantation of the tissue.

II. CLINICAL SIGNIFICANCE:

A. The reporting of an adverse outcome of tissue transplantation by the surgeon and the subsequent investigation by the Transfusion Medicine and the tissue bank are critical responsibilities for the safety of tissue transplantation. Without the reporting of adverse outcomes or complications, correctable defects would not be discovered, preventable actions could not be implemented, and as result, other patients could be at potential risk.

III. DEFINITIONS:

A. **Variance**: Event detected that may be error, accident, complaint, unplanned deviation, or incident that is documented for review, evaluation, investigation, and correction.

B. **Adverse Outcome**: An undesirable effect or untoward complication in a recipient consequent to or reasonably related to cell and/or tissue transplant.

C. **Complication**: Any written or oral communication concerning dissatisfaction with the identity, quality, packaging, durability, reliability, safety, effectiveness, or performance of cells and/or tissue.

IV. PROCEDURE:

A. Upon notification of an adverse outcome, disease transmission, or other complication, perform the steps in the tables below to accomplish the following:

1. Recipient identification and/or notification as indicated
2. Complete documentation of notification and follow-up activitie

B. **Table 1: Document verbal or written notification by the surgeon or Infection Control**

1.

Step	**Action:** Performed by Blood Bank medical Technologist	Notes
1	Submit an Internal Variance Form	a. Internal variance form can be accessed within each site specific Sharpoint page. Refer to Blood Bank Policy, Variance Reporting.
2	Notify the Medical Director or Tissue Coordinator of the adverse outcome	a. Document the details of the notification on the variance report including: • complete name of the person contacted • date & time of the contact

C. **Table 2: Initiated Tissue Adverse Outcome Investigation Report**

1.

Step	**Action:** Performed by Tissue Coordinator	Notes
1	Complete Tissue Adverse Outcome Investigation Report.	a. Applicable sections: • General Information & Discovery • Transplanting Surgeon • Tissue

Step	**Action:** Performed by Tissue Coordinator	Notes
		Information • Suspect Adverse/ Reaction Description • Tissue Supplier(s) Involved • Notification
2	Acquire microbiology results if applicable.	
3	Direct completed form to the Medical Director/Associate Medical Director or designee.	

D. **Table 3: Medical Director Review**

1. Determine follow-up activities based upon, notification from Infection Control and/or risk classification as assigned by the Medical Director/Associate Medical Director or site specific designee.

a.

Designee	Follow-up Activities	Notes
Medical Director or Associate Medical Director	Evaluate the suspect adverse outcome: 1. Complete Investigative Response section. 2. Direct Tissue Coordinator to perform any follow-up activities. 3. Close report.	
Medical Director or Designee	Notification of sero-conversion for disease marker of tissue transplant recipient: 1. Notify the	• Mandatory reporting of adverse reaction related to human cells, tissues, and cellular and tissue

Designee	Follow-up Activities	Notes
	tissue supplier immediately upon discovery. 2. Notify FDA through MedWatch. MedWatch Form 3500A: Mandatory Reporting of Adverse Reactions to HCT/Ps	based products(HCTPs) can be accomplished online at: https://www.fda.gov/Biolo gicsBloodVaccines/Safet yAvailability/ReportaProbl em/ucm152576.htm
Medical Director or Designee	Notification of suspect bacterial infections as reported by Infection Control in which the causative agent may be the donor tissue: 1. Contact the attending physician by telephone of suspect infection that may be the result of the transplanted tissue. 2. Document each attempt to contact the attending physician in the record with the outcome of the contact. 3. Make reasonable attempts in writing or by	Confirm with the physician the requirement for notification of the patient if indicated (or legal representative or relative if the patient is a minor, or adjudged incompetent by a State court). • Provide a basic explanation to the physician of the risk for disease transmission, need for additional testing, referral for counseling and documentation of each.

Designee	Follow-up Activities	Notes
	telephone to notify the patient directly, the attending physician or the physician who ordered the tissue within 12 weeks after being notified by the supplier and document in the record.	

E. **Table 4: Record Storage/ Retention**

1. Records will be maintained following confidentiality requirements as stated in Laboratory Document Management and Record Retention Procedure and stored for a minimum of 10 years from the date of final disposition, in a manner that permits prompt retrieval

a.

Designee	Action	Notes
Tissue Coordinator/ Site Specific Tissue Management Medical Technologist	File completed Tissue Adverse Outcome Investigation Report form in the Tissue Adverse Outcome Investigation Report Tissue Recall / Market Withdrawal / Adverse Outcome log located in the Tissue Management office.	Records are kept onsite for a minimum 2 years and then transported to Transfusion Medicine record storage for a minimum of 10 years.

V. REFERENCES:

1. AABB, Standards, current edition
2. American Association of Tissue Banks, Standards, current edition
3. https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/ucm152576.htm (accessed March 15, 2019)
4. FDA: 21 CFR 600.12 Records
5. FDA: 21 CFR 1271.350(a) Current good tissue practice for human cell, tissue, and cellular and tissue-based product establishments: inspection and enforcement: final rule.

6. FDA: Guidance for Industry: MedWatch Form 3500A: Mandatory Reporting of Adverse Reactions to HCT/Ps
7. FDA Form 3500 access: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.p df (accessed March 15, 2019)

Attachments

Tissue Adverse Outcome Investigation Report Form

Approval Signatures

Step Description	Approver	Date
	Vaishali Pansare: Chief, Pathology	9/5/2023
	Ryan Johnson: OUWB Clinical Faculty	9/1/2023
	Kristina Davis: Staff Physician	8/30/2023
	John Pui: Chief, Pathology	8/29/2023
Policy and Forms Steering Committe (if needed)	Wendy Frizzo: Bone and Tissue Coordinator	8/29/2023
	Teresa Lovins: Supv, Laboratory	8/29/2023
	Karrie Torgerson: Supv, Laboratory	8/29/2023
	Kelly Sartor: Mgr, Division Laboratory	8/29/2023
	Wendy Frizzo: Bone and Tissue Coordinator	8/29/2023
	Wendy Frizzo: Bone and Tissue Coordinator	8/29/2023