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Tissue Supplier Notification of Recall/Market Withdrawal

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. Tissue products shipped to Corewell Health which are subsequently determined unsuitable for transplantation can be *recalled or withdrawn by the tissue bank or intermediary supplier*.

B. The purpose of this document is to establish a standardized, consistent process for Blood Bank staff to follow when a tissue bank or intermediary supplier notifies the Blood Bank of a non-conforming product(s). The process is intended to promote prompt removal and quarantine of the product from the available inventory; to act as a guide for suitable follow-up activities such as return or discard of a product as indicated by the supplier; and to initiate prompt notification of appropriate persons in the event the product may have a potential infectious disease transmission risk.

II. POLICY:

A. The following policies outline responsibility for removal of a non-conforming product from available inventory, subsequent handling of the affected product and prompt notification of the recipient as indicated.

1. The Blood Bank will develop agreements with suppliers to notify us if it supplied our facility with potentially infectious tissue.
2. A Medical Technologist will handle all verbal supplier notification calls to determine the availability/transfusion status of the product, immediately place any available product into the quarantine status in the blood bank computer system, physically remove and quarantine any affected product from available inventory, document supplier notification on Blood Bank form, Blood Supplier Notification (located in policy Supplier Notification of Recall/Market Withdrawl/Lookback) , and identify recipients of any transfused/implanted product if indicated.

3. Products subsequently determined unsuitable for use shall be returned or discarded as instructed by the supplier.
4. The Transfusion Service Medical Director/Associate Director will assess risk to recipients and the likelihood of infectious disease transmission to determine appropriate physician/patient notification
5. Disposition/notification information requested by the supplier will be submitted to the supplier as soon as possible.
6. Reasonable attempts to notify a recipient who received a tissue product from a donor who is later determined at risk for transmission of infectious disease, will be completed in a timely manner as indicated in Food and Drug Administration (FDA) rules and regulations.
7. Notification and/or efforts to notify will be documented.
8. Records of the source and disposition of all tissue products will be maintained for a minimum of ten years from the date of disposition in a manner that permits prompt retrieval.
9. The term *lookback*, by definition, does not apply to tissue products.
10. In addition to Blood Bank form, Blood Supplier Notification, the tissue coordinator will document Blood Bank form*, Tissue Adverse Outcome Investigation Report,* as necessary.

III. DEFINITIONS:

A. **Consignee**: Anyone who received, purchased, or used the product being withdrawn or recalled.
B. **Recall**: A firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (recall does not include a market withdrawal).
C. **Market Withdrawal**: A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation.
D. **Lookback**: The process of identifying the current location and/or final disposition of components from a particular donor, removing from inventory any components that are potentially infective or, in the case of transfused products, identification of the recipient if indicated, so that appropriate treatment and counseling can be provided. (Lookback is usually initiated by detection of a confirmed reactive viral marker result on a donor who previously tested negative or who last donated prior to inclusion of that test in the routine screening protocol).
E. **Transplant Recipient Notification**: The actions taken by a hospital, transfusion service, or patient's physician of record to notify patients that they have received transfusion or implant of a product that is at increased risk of disease transmission.
F. **Low Risk (Class III)**: Situation in which use of, or exposure to, a violative product is not likely to cause adverse consequences.
G. **Moderate Risk (Class II)**: Situation in which use of, or exposure to, a violative product may

cause temporary or medically reversible health consequences or where the probability of serious adverse health consequences is remote.

H. **High Risk (Class I)**: Situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

IV. PROCEDURE:

Perform the steps below to accomplish the following:

A. Appropriate inventory management of products targeted for recall/market withdrawal.

B. Recipient identification and/or notification as indicated.

C. Complete documentation of notification and follow-up activities.

D. **Verbal notification by supplier of recall/market withdrawal (performed by the Medical Technologist):**

1. Document recall/market withdrawal information on Section A: Notification and Product Information of Blood Bank form, *Blood Supplier Notification,* (located in policy Supplier Notification of Recall/Market Withdrawl/Lookback).
2. If the notification was made by phone, document the caller's name and request a follow-up fax or e-mail with the information.
3. Document the following information:
    a. Blood Bank employee name
    b. Date and time of notification
    c. Type of notification
    d. Name of supplier
    e. Reason for notification for recall/market withdrawal if applicable
    f. Type tissue involved: (i.e. crush cancellous, Achilles tendon, etc)
    g. Product identification: (i.e. unique identifier & product reorder code)
4. Determine status of the product:
    a. **If product is in-date, not transplanted:**
        i. Release the product from crossmatch if applicable.
        ii. Place the product(s) into quarantine status in the blood bank computer system.
        iii. Physically quarantine the product(s) from available inventory and attach a copy of the supplier notification to the quarantined product.
        iv. List the quarantined product(s) and information on communication log/board.
        v. Print and attach the Unit History Report, indicating the "quarantine" status to Blood Bank form, *Blood Supplier Notification,* (located in policy Supplier Notification of Recall/

Market Withdrawl/Lookback).

b. **If the product has been transplanted:**

i. Document the recipient's name and MRN and print a Unit History Report from the blood bank computer system.

ii. Attach the report to Blood Bank form, *Blood Supplier Notification,* (located in policy Supplier Notification of Recall/ Market Withdrawl/Lookback).

c. **If the product is expired/discarded:**

i. Document the day in which the product expired or discarded, and print a Unit History Report from the blood bank computer system.

ii. Attach the report indicating the "discard" status to the form.

5. Create a record of Recall/ Market Withdrawal:
   a. Place the form and attached documentation for review by the Medical Director or site specific designee.
   b. For Royal Oak campus, place a copy of the form with attached documentation of product quarantine or disposition in the Hospital Tissue Coordinator mailbox.
   c. Indicate the record is a copy by stamping 'copy' on the form.

E. **Tracking of supplier of recall/market withdrawal (performed by QA or designee):**
   1. The site specific QA or QA designee will review Section A and Section B of Blood Bank form, *Blood Supplier Notification,* for completeness and make any necessary corrections.
   2. Place the pending form in the site specific storage location while waiting for the written notification by the supplier that supports the verbal communication.
   3. Alert the Transfusion Medicine Medical Director for high risk issues (reasonable probability that exposure will cause serious adverse health consequences or death), document date/and time.

F. **Tracking of supplier of recall/market withdrawal (performed by clerical staff or designee):**
   1. Retrieve product record from the site specific storage location.
   2. Attach written/fax notification from the supplier to Blood Bank form, *Blood Supplier Notification*.
   3. Document the component disposition on the form provided by the supplier and return as soon as possible.
   4. Attach a copy of the supplier disposition form to the *Blood Supplier Notification* form.
   5. Return the "pending" form, to the site specific storage location for further follow up.

G. Determine follow-up activities based upon the status of the product, instructions from the

supplier, and risk classification as assigned by the Medical Director/Associate Medical Director or site specific designee.

Designee	Follow-up Action
Medical Technologist	**If the supplier determines the product to be acceptable for use:** 1. Retrieve the “pending” Blood Bank form, *Blood Supplier Notification*, from the site specific storage location. 2. Document name of person authorizing release of product. Return product to available inventory in the blood bank computer system. 3. Print computer documentation for transition of the product from “quarantine” to “available” status and attach to the form. 4. Physically remove product from quarantine location to available inventory shelf. Return the form to the site specific storage location.
Tissue Coordinator/Blood Bank Supervisor	**If the supplier instructs discard of product:** 1. Retrieve “pending” Blood Bank form, *Blood Supplier Notification*, from the site specific storage location. 2. Document name of person authorizing destruction of product as well as the date and time. 3. Discard product in Blood Bank IS. 4. Print computer documentation for transition of product from “quarantine” to “discard” status and attach to the form. 5. Physically discard product. 6. Return the form to the site specific storage location.
Tissue Coordinator/ Blood Bank Supervisor	**If the supplier sends written letter providing additional donor testing information:** 1. Retrieve “pending” Blood Bank form, *Blood Supplier Notification,* from the site specific storage location.

	2. Attach additional information to the form. 3. Return the form to the site specific storage location.
Tissue Coordinator/Tissue Management Medical Technologist	**Follow up activities when supplier provides additional donor testing information:** 1. Assign a temporary risk category based upon the potential for infectious disease transmission and patient notification recommendation by supplier. a. **Low risk (Class III)**: Exposure to the product is unlikely to cause adverse consequences to the recipient. b. **Moderate risk (Class II)**: May cause temporary reversible health consequences or where the probability of serious adverse health consequences is remote. c. **High risk (Class I)**: Reasonable probability of serious adverse health consequences or death. 2. Submit information documented on Blood Bank form, *Blood Supplier Notification,* to the Transfusion Medicine Medical Director for review and final determination of risk assessment.
Medical Director or Site Specific Designee	**Assess Physician/Patient notification requirements:** 1. Assess the risk to the recipient and determine the extent of notification required based upon the status of the patient. 2. Contact the patient's attending physician to discuss the findings and determine whether the recipient should be notified and whether additional testing is indicated. a. If the recipient is deceased, the requirement to notify the legal guardian or relative of possible exposure applies only to HIV infection and not HCV infection. 3. Provide sufficient information regarding the

	recall and the reason for the recall to allow the physician to evaluate the patient's condition and provide appropriate patient care.

H. **Transplant Notification Guidelines**: Notify the patient, the attending physician, or the physician who ordered the tissue that potentially infectious tissue was implanted and that the patient may need additional testing and/or counseling.

Designee **Follow-up Action**	
Medical Director or Site SpecificDesignee	1. Contact the attending physician by telephone for high risk patients. 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 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. **Note:** 1. 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). 2. HIV recall: Notification of legal guardian or relative is required even if the patient is deceased. 3. Provide a basic explanation to the physician of the risk for disease transmission, need for additional testing, referral for counseling, and documentation of each.
Medical Director or Site Specific Designee	**If the physician agrees to notify the recipient:** 1. Document the physician's name, date and time of agreement and the name of the person obtaining agreement. 2. Send a letter to the physician confirming that he/she agreed to notify the patient (relative or legal representative) of the recall, explain the risk of disease transmission, and refer for counseling.

	3. Copy the letter, include the date of mailing and attach to Blood Bank form, *Blood Supplier Notification*.
Medical Director or Site Specific Designee	**If the physician is unavailable or declines to make the notification:** 1. Make reasonable attempts to notify the patient (relative or legal representative) by telephone or by mail of the recall using information from the hospital information system within 12 weeks after being notified by the supplier and document in the record. 2. Document the date and time of each attempt to notify.
Medical Director or Site Specific Designee	**Notification of sero-conversion for disease marker of tissue transplant recipient:** 1. Perform an investigation of the adverse event. a. Refer to Transfusion Medicine policy, *Tissue Complication Adverse Reaction.* 2. Notify the tissue supplier immediately upon discovery. 3. Notify FDA through MedWatch. a. Mandatory reporting of adverse reaction related to human cells, tissues, cellular and tissue based products (HCTPs) can be accomplished on-line at the web address in the Reference Section of this policy.

I. **Record Storage/ Retention (Performed by Clerical and QA Staff)**: 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.

1. If the product was released and subsequently returned to available inventory:
   a. File completed record of notification and subsequent return to available inventory as documented on Blood Bank form, *Blood Supplier Notification*, with other internal variance reports.
2. If the product was discarded or returned to the supplier:
   a. File completed record of notification and discard as documented on Blood Bank form, *Blood Supplier Notification*, with recall/market withdrawal records.
      i. Records are kept on site for 2 years and then transported to Blood Bank record storage for a minimum of 10 years.

3. If physician/patient notification was required:
    a. File completed record of notification as documented on Blood Bank form, *Blood Supplier Notification*, with lookback records.
        i. Records are kept on site for 2 years and then transported to Blood Bank record storage for a minimum of 10 years.

V. REFERENCES:

1. FDA: 21 CFR 600.12 Records
2. FDA: 21 CFR 1271.35 (a) Current good tissue practice for human cell, tissue, and cellular and tissue-based product establishments: inspection and enforcement: final rule.
3. FDA: 21 CFR 1270.44 Retention, recall and destruction of human tissue
4. FDA: 21 CFR 7.3 Definitions
5. FDA:21 CFR 7.49 (d) Responsibility of recipient
6. Human Cell & Tissue Products (HCT/P) Adverse Reaction Reporting
7. AABB, Standards, current edition
8. American Association of Tissue Banks, Standards, current edition

Approval Signatures

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