Handling of Autologous Tissue

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide the laboratory staff with specific guidance for accepting autologous tissues from surgery into Transfusion Services. Compliance to this procedure will promote the quality and integrity of the autologous tissue.

II. CLINICAL SIGNIFICANCE:

Autologous tissue intended for re-implantation and storage may arrive at Transfusion Services from surgery. Incoming tissue shall be inspected, and documentation of receipt must be recorded electronically in the Transfusion Medicine information system (IS) for traceability and integrity. Transfusion Services may receive, store, and issue autologous tissue for the intended patient only.

III. DEFINITIONS:

A. **Autologous**: Cells and/or tissue intended for implantation, transportation or infusion into the individual from whom they were collected.

B. **Designee**: The designee is the Medical Technologist at Farmington Hills, Grosse Pointe, and Royal Oak . The designee is the Blood Bank technical director, or transfusion medicine fellow at Troy.

IV. SPECIMEN HANDLING:

Autologous bone or skin may be procured in the operating room from a patient for future implantation. Tissue containers must be clearly labeled with the following:

A.   Patient's complete name

B.   Medical Record Number (MRN)

C.   Birthdate

D.   Date of tissue removal from patient

E.   Procuring surgeon

F.   Contents: 1 of 2, right flap, etc.

V. SPECIAL SAFETY PRECAUTIONS:

Tissues are bio-hazards. Any broken packaging or compromised tissues should be handled using standard precautions. Autologous tissue is not disease marker tested nor is it processed or changed in anyway.

VI. PROCEDURE:
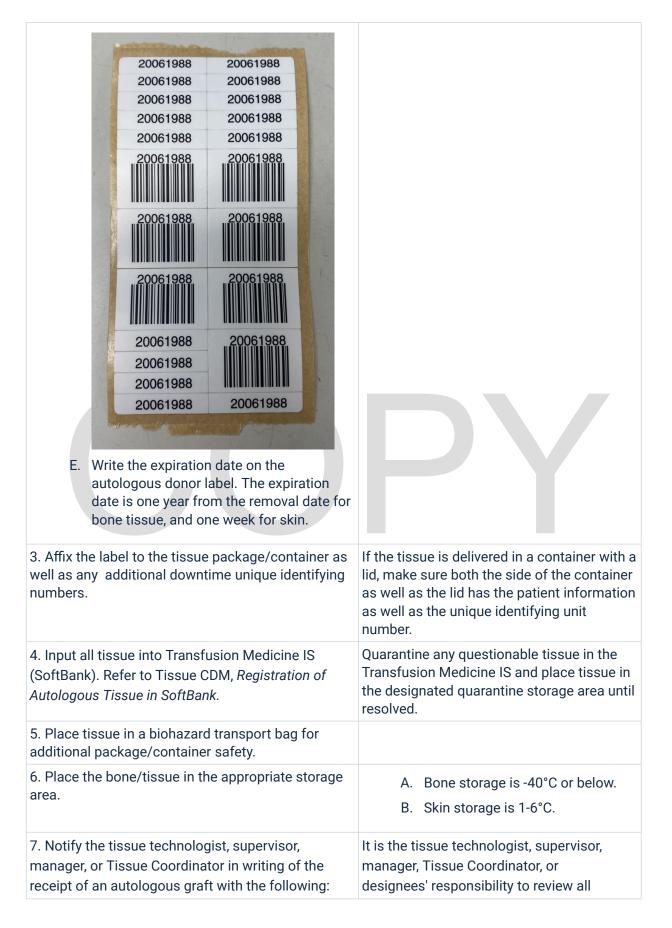
A. RECEIPT AND INSPECTION OF TISSUE:

Action	Notes
1. Inspect the container for damage and proper identification of the patient: A. Patient's complete name B. MRN C. Birthdate D. Date of tissue removal E. Procuring surgeon F. Contents: 1 of 2, right flap, etc	Tissue may be inadvertently dropped off at other locations in the laboratory. Instruct the recipient of the tissue to bring the tissue to Transfusion Services and inform the blood bank technologist that an autologous tissue was received and needs to be processed for storage. If autologous tissue cannot be received at the time of delivery, the technologist should inspect the graft for proper labeling and put the autologous tissue in its proper storage area. Add a tissue comment in SoftBank indicating the reciept of the autologous skin or bone.
2. Complete the Autologous Donor label (Green sticker: 7205 JAN OS). A. Document patient's name, medical record number and date of surgery at the bottom of the label. B. Cross out "AS-5 Red Blood Cells" box and add the description of the contents of the container on the Autologous Donor label. Example:	Note: any discrepancies in the receipt of the autologous tissue on a variance and notify the Supervisor, Lead Technologist, Tissue Technologist, or the Corporate Tissue Coordinator regarding the submission of the variance. Refer to Transfusion Medicine policy, Variance Reporting.

C. Affix an 'AUB' (for bone) or 'TUS' (for skin) bar-code label to the product code area on the Autologous Donor label.

D. Affix a downtime unique identifying number sticker to the unit number area on the Autologous Donor label.

E. Write the expiration date on the autologous donor label. The expiration date is one year from the removal date for bone tissue, and one week for skin.

3. Affix the label to the tissue package/container as well as any additional downtime unique identifying numbers.	If the tissue is delivered in a container with a lid, make sure both the side of the container as well as the lid has the patient information as well as the unique identifying unit number.
4. Input all tissue into Transfusion Medicine IS (SoftBank). Refer to Tissue CDM, *Registration of Autologous Tissue in SoftBank*.	Quarantine any questionable tissue in the Transfusion Medicine IS and place tissue in the designated quarantine storage area until resolved.
5. Place tissue in a biohazard transport bag for additional package/container safety.	
6. Place the bone/tissue in the appropriate storage area.	A. Bone storage is -40°C or below. B. Skin storage is 1-6°C.
7. Notify the tissue technologist, supervisor, manager, or Tissue Coordinator in writing of the receipt of an autologous graft with the following:	It is the tissue technologist, supervisor, manager, Tissue Coordinator, or designees' responsibility to review all

A. Patient's complete name B. Medical record number C. Birthdate D. Date of tissue removal E. Procuring surgeon F. Contents: 1 of 2, right flap, etc G. Mark note as 'receipt completed' or 'receipt incomplete- needs attention'.	autologous tissue submissions for proper labeling, storage, and integrity once the storage process is completed by the technologist.

B. FINAL DISPOSITION OF AUTOLOGOUS TISSUE:

Re-implantation processes are as follows: 1. Refer to Transfusion Medicine policy, Issue of Tissue. 2. Refer also to Blood Bank Tissue CDMs, Ordering Tissues Using Epic or Ordering Tissues Using SoftLab, *Selecting Tissue for Issue*, and Issuing Tissue.	A. Frozen bone will be transported on dry ice. B. Refrigerated tissue will be sent in a cooler with an ice pack.

Discard process of autologous tissue from a deceased patient:
 	
1. Confirm patient death.
 	
    1. Access Epic.
 	
    2. Access Hospital Chart.
 	
    3. Enter medical record number of the patient. EPIC alerts the user that you are about to enter a deceased person's chart.
 	
    4. Create a screen shot of Epic screen with the patient's status.
 	
2. Add an additional patient message under **TISCM** that states the 'patient is deceased' with the date of the last discharge of the patient. Refer to Blood Bank CDM, *Add/Delete/Edit/ Inactivate Patient Messages*.	

3. Add a unit comment that states the 'patient is deceased'. Refer to Blood Bank CDM, *Adding a Unit Comment*.

4. Perform discard of autologous tissue in Transfusion Medicine IS. Refer to Blood Bank CDM, *Edit Unit Status*.

    1. Use Discard Code: PTCHG - Change in Patient Status

5. Print the Unit History report for the Blood Bank IS. See Blood Bank CDM, *Unit History Report*.

6. A cosigner must confirm patient name, date of birth, MRN, and confirmation of death. Both cosigner and technologist must sign and date the Unit History report.

7. Attach the Epic screen print of the patient's status to the autologous unit history, and file with paper discard records.

8. Physically discard the autologous tissue in a red biohazard bin.

Release of autologous tissue from a deceased patient to funeral home:

1. Confirm patient death in Epic: Hospital Chart > enter medical record number of the patient.

2. Perform Tissue procedure, *Issue of Tissue*. Refer to Tissue CDMs, *Ordering Tissues Using Epic* or *Ordering Tissues Using SoftLab, Selecting Tissue for Issue, and Issuing Tissue*.

3. Release and document the full name and badge ID of the hospital personnel taking the autologous bone flap on the *Tissue Graft Information* form.

4. Add a written comment on form, *Tissue Graft Information,* stating the following:
'The patient is deceased and the

A. Family of a deceased patient may request the autologous bone flap collected in operating room to be sent to the funeral home with the patient. This notification may come from the floor, funeral home, the bereavement representative, or surgical services. Autologous bone flaps may only be released to hospital personnel.

B. If Transfusion Medicine is notified of a request for an autologous bone flap from the funeral home, contact the area the patient is currently on or has been discharged from and provide the hospital staff with the name of the funeral home, phone number, and contact name.

autologous bone flap is being released to (hospital staff ID#) as requested by the family.' Initial & date the comment.

5. Add a unit comment that states 'The patient is deceased and the autologous bone flap is being released to (hospital staff ID#) as requested by the family.' Refer to Blood Bank CDM, *Adding a Unit Comment*.

6. Allow the unit to go to the transfused status.

7. File the form, *Tissue Graft Information,* appropriately, ensuring the pink copy is sent to medical records.

Audit and discard of expired autologous tissue:

1. Review the autologous tissue in inventory periodically.

2. Identify all expired units and units of expired patients.

3. Discard unit of expired patients using discard process of autologous tissue from a deceased patient in this document.

4. Investigate all expired autologous units.

5. Contact procuring physician with the form letter regarding status of tissue. See attachments.

6. Discard or continue to save as directed by the patient's physician.

7. Perform discard of autologous tissue upon doctor's request in Blood Bank IS. Refer to Blood Bank CDM, *Edit Unit Status*.

8. Add a unit comment that states the doctor's response. Refer to Blood Bank CDM, *Adding a Unit Comment*.

9. Refer to Blood Bank CDM for

discards, *Edit Unit Status*. Use Discard Code: PTCHG - Change in Patient Status

10. Print the Unit History report for the Blood Bank IS. Refer to Blood Bank CDM: Unit History Report.

11. A cosigner must confirm patient name, date of birth, MRN, and reason for discard. Both cosigner and technologist must sign and date the Unit History report.

12. Attach the status of autologous tissue doctor's letter to the autologous unit history and file with paper discard records. See site specific letters attached to this policy.

13. Physically discard the autologous tissue in a red biohazard bin.

VII. REFERENCES:

1. 21. CFR 1271: Human cells, tissues, and cellular and tissue based products. April 2013. US Food and Drug Administration.Tissue Establishment Registration

2. AABB, Standards for Blood Banks and Transfusion Services, current edition.

3. American Association of Tissue Banks, Standards for Tissue Banking, current edition.

Attachments

FH Tissue Form - Letter to Doctor RE: Autologous Bone.pdf

GP Tissue Form - Letter to Doctor RE: Autologous Bone.pdf

RO Tissue Form - Letter to Doctor RE: Autologous Bone .pdf

Troy Tissue Form - Letter to Doctor RE: Autologous Bone.pdf

Approval Signatures

Step Description	Approver	Date

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