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| **University of Washington,** **Harborview Medical Center****325 9th Ave. Seattle, WA, 98104****Transfusion Services Laboratory****Policies and Procedures Manual** | **Original Effective Date:** **March 10, 2014** | **Number:** **C5005-1** |
| **Revision Effective Date:** | **Pages: 3** |
| **TITLE: Discarding Autologous Bone**  |

**Purpose**

To provide instruction for processing returned autologous bone and discarding autologous bone.

**Procedure**

**A: Monitoring Inventory and Discard Criteria**

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| **Step** | **Action** | **Related Documents** |
| **Monitor Inventory** |
| 1. | Weekly:Inspect inventory for:* Bone that exceeds the 24 month storage limit.
* Damage or loss of integrity of a bone package.
* Quarantine storage area for bone packages under investigation for possible discard
* Complete QIM and PSN if bone package fails visual inspection.
 | * Quality Improvement Monitoring form (QIM)
* Patient Safety Net (PSN)
 |
| 2. | Proceed to Discarding Bone section. |  |
| **Returned Autologous Bone** |
| 1. | OR staff returns bone package **within 20 minutes**:* Inspect bone package for integrity and clear labeling
* Update Tissue Tracking Record and Autologous Bone Tracking Log with “returned to inventory, date/time, tech ID”
* Place bone package in storage
* File Tissue Tracking Record in Inventory binder, alphabetically.
 |  |
| 2. | OR staff returns bone package **after 20+ minutes**:* Ask OR staff if re-implantation is anticipated. Note response on Quarantine form.
* Rubber band a time stamped Quarantine form to the autologous bone package
* Place bone package in the Quarantine storage area
* Complete QIM and PSN
* Proceed to Discarding Bone section.
 | * Quality Improvement Monitoring form (QIM)
* Patient Safety Net (PSN)
 |
| 3. | Shipped Bone Package to an outside facility is returned* Inspect transport container for intact seals, adequate dry ice, and closure integrity.
* Note condition “acceptable / unacceptable, date/time, tech ID on the Quarantine form
* Rubber band a time stamped Quarantine form to the autologous bone package.
* Place bone package in the Quarantine storage area
* Complete QIM.
* Proceed to Discarding Bone section
 | * Quality Improvement Monitoring form (QIM)
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| **Step** | **Action** | **Related Documents** |
| **Positive Cultures** |
|  | * Positive aerobic or anaerobic culture results
* Review completed Notification of Release of Non-Conforming Autologous Bone form attached to the Tissue Tracking Record. Physician marked:
	+ Use this Product: Move bone package to non-conforming area of the ultra low freezer
	+ Decline to use this product/please discard: Proceed to Discarding Bone section.
 | Notification for Release of Non-Conforming Autologous Bone form |
| **Patient Expires** |
|  | Weekly:* Review the Deceased Patient Notification forms.
* Compare to the Autologous Bone Tracking Log
 |  |
|  | If patient has autologous bone in storage:* Attach a time stamped Quarantine form to the bone package
* Note on form “Expired (date), Tech ID”
* Relocate autologous bone package
* Proceed to Discarding Bone section.
* *Note: Autologous Bone from expired patients will be held in quarantine a minimum of 2 weeks from the date of death in case the patient’s family requests the bone.*
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| **Temperature failure of the storage device such that the tissue is out of temperature.** |
|  | * Every effort will be made to move autologous bone to the back up ultralow freezer.
* Additional efforts may include temporary storage in other freezers or on dry ice.
* Quarantine Autologous Bone packages that are out of temperature for > 20 minutes until a determination can be made by the TS Medical Director about their final disposition.
	+ Rubber band a time stamped Quarantine form.
	+ Move the bone package to a Quarantine storage area.
	+ Complete QIM and PSN
	+ Proceed to Discarding Bone section.
 | * Quality Improvement Monitoring form (QIM)
* Patient Safety Net (PSN)
 |
| **Autologous Bone will not be Re-implanted** |
|  | Notification by phone, letter, and/or email that Autologous Bone will not be re-implanted:* Attach a time stamped Quarantine form to the bone package
* Note on form “Will not be re-implanted per (clinical staff), date/time, Tech ID”
* Relocate autologous bone package to Quarantine storage area
* Proceed to Discarding Bone section.
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**B: Discard**

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| **Step** | **Action** | **Related Documents** |
| **Discarding Bone** |
| 1. | **Complete Notification for Discard form*** + Electronic form
	+ Save to Lilith 2 folder
* Patient and Bone Package information
	+ Date/Time
	+ Patient Name and MRN number
	+ Unique Identification number of bone package
	+ Collection date/time
* Check Reason for Discard
	+ Exceeds the 24 month storage limit
	+ Out of temperature monitored freezer for longer than 20 minutes with no intent to re-implant at that time
	+ Damage or loss of integrity of bone package
	+ Patient expired
	+ Failure of the temperature monitored storage freezer
	+ Product returned to TSL after transport to outside facility
	+ Other
* Print 2 copies.
* Complete Notification Letter.
* Forward form to the neurosurgeon along with a Notification Letter requesting a signature and return to TSL.
* Staple a copy to the Tissue Tracking Record.
* File in the Autologous Bone Pending notebook.
 | On Lilith2:* Notification Letter
* List of neurosurgeons’ contact information
 |
| 2. | Weekly:* Review the pending notifications.
* If no response in 2 weeks, re-send the notification to the neurosurgery attending.
* If no response, forward to Medical Director.
 |  |
| 3. | Once the signed notification is returned to TSL or 4 weeks has passed:* + Forward to TSL Manager/Medical Director for signature.

After TSL Manager/Medical Director signature:* + Update the Tissue Tracking Database, Tissue Tracking Record, and the Autologous Bone Tracking Log.
	+ A 2nd tech verifies and reviews all paperwork and bone package label against the discard form.
	+ Discard bone package in a grey tissue disposal bin in the OR dirty utility room.
	+ Staple the completed form to the Tissue Tracking Record.
	+ Move Tissue Tracking Record to the Tissue Discard binder.
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**References:**

Standards for Blood Tissue Banking, Current Edition, American Association of Tissue Banks. AATB, Bethesda, MD.