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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:** **C5003-1** |
| **Revision Effective Date:** | **Pages:** 4 |
| **TITLE: Maintaining and Issuing Autologous Bone for Re-implantation** |

**Purpose**

To provide instructions for maintaining autologous bone for potential re-implantation. Provide instructions for issue from and return to Transfusion Services Laboratory of autologous bone.

**Policy**

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| **Step** | **Action** | **Related Documents** |
| Chain of Custody | * Transfusion Service Laboratory (TSL) staff signs for and receives autologous bone for storage after patient identification verification with OR designee.
* TSL maintains a log and database of autologous bone storage location and disposition.
* TSL documents release of autologous bone for implantation to OR designee only after verification of patient identification.
* TSL discards and documents permission to discard autologous bone according to policy.
 | * Autologous Bone Process
* Table A: Database Maintenance
* Table B: Culture Results
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| Storage | * Autologous Bone is stored in the Autologous Bone Freezer at minus 80°C in TSL
* Freezer is equipped with continuous temperature monitoring and alarm.
* Daily documentation of temperatures
* 24/7 alarm response.
* Maintenance of Back-up freezer in OR in case of equipment failure of primary bone storage ultra-low freezer.
 | * Using the Temp Trak System
* Maintenance and QC of Ultralow Freezer
* Responding to Temperature Alarms
 |
| QIM and PSN completion | * At any point in the receipt, storage, and issue process, a QIM and PSN should be completed if the autologous bone cannot be re-implanted.
* This includes but is not limited to:
	+ Bone package is damaged
	+ Patient identifiers do not match during read back
	+ Failure of storage units to maintain appropriate temperature
 | * QIM
* PSN
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**Procedure**

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| **Step** | **Action** | **Related Documents** |
| **Maintenance** |
| 1. | Designated TSL staff will:* Update database
* Review culture results for autologous bone.
* Complete processing based on culture results

*Note: Culture reports are finalized about 7 days after collected* | * **Table A**: Database Maintenance
* **Table B:** Culture Results
 |
| 2. | **Surgical Schedule** * Review daily surgery schedule for potential re-implantations.
* Verify acceptability of bone for impending re-implantations
* Post information on erasable board near tube station
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| 3. | **Monitor Expiration Dates*** Monitor bone expiration date for discard.
 | Discarding Autologous Bone |

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| **Request for and Release of Bone for re-implantation** |
| **OR Staff** | * Provides notification of intent to re-implant tissue
* Arrives in TSL with Bone Release form or “tubes” form to TSL
* Participates in 2 person “read-back” of patient Identifiers on Bone Release form and bone package label
 | Bone Release form |
| **TSL Staff**1. | * Locate the **Tissue Tracking Record** using the patient identifiers from the Bone Release form.
* Remove the corresponding autologous bone package from the freezer.
* Perform visual inspection of the autologous bone package.
* Verify patient identifier match.
* Verify that unique number label on the autologous bone package matches the number label on the Tissue Tracking form.
* Record Bone Sample cryo number and visual inspection on the Bone Release form
* Answer Non-conforming Product question by assessing presence of non-conforming form attached to the Tissue Tracking Record.
 | Tissue Tracking RecordNotification for Release of a Non-Conforming Autologous Bone form |
| 2. | **In TSL*** Perform a 2 person verification of patient identifiers and unique cryo number of the following:
* Bone Release form
* Cryo label
* Autologous Bone Tracking Log
* Tissue Tracking Record
* Record Tech IDs on the Bone Release form
 | Receipt of Autologous Bone for Re-Implantation |
| **Request for and Release of Bone for re-implantation (continued)** |
|  | **Action** | **Related Documents** |
| 3. | * Record the following on the **Autologous Bone Tracking Log:**
* Date/time of removal
* Issuing TSL tech ID
* Issued to: Receiving OR personnel
* Attach one copy of Bone Release form to the Tissue Tracking Record
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| 4. | **Attach Autologous Bone Implantation Warning**:* + Record TIME OUT on form
	+ Rubber band form to bone package
 | Implantation Warning |
| 5. | **In O.R.*** Perform and record 2 person verification on Bone Release form
* Return to TSL with one copy of Bone Release form
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| 6. | Place Tissue Tracking Record and attached Bone Release form in Issued section of the binder, alphabetically. |  |

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| **Transfusion Service Return of Autologous Bone from O.R.** |
|  | **Action** | **Related Documents** |
| 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
* Proceed to Discarding Bone SOP.
* Complete a QIM.
 | Quality Improvement Monitoring tool (QIM) |

**References:**

Standards for Tissue Banking, Current edition, American Association for Tissue Banks. AATB,

Bethesda, MD.

**Table A: Database for Autologous Bone: Maintenance**

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| **Access Excel Spreadsheet** | 1. My Network Places
2. HMC\_TSS on Lilith.labmed.washington.edu
3. From\_Lapis\_H\_drive
4. Tissue Bank
5. Autologous Tissue Tracking
6. Master Tissue Tracking Database (Current Inventory)
7. Password: CrashCranis321
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| **Filling out Excel Spreadsheet** | 1. Obtain Tissue ID, Patient Name, MRN, Surgery Date, Surgeon, Tissue Type & Date/Time in Freezer from Tissue Tracking Log.
2. Don’t worry about Social Security numbers
3. Obtain Culture Accession # & Results from Laboratory Inquiry
4. Comment area to be filled out once culture results given.
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**Table B: Culture Result Processing**

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| **Obtaining Culture Accession #**  | 1. Open SQ
2. **Function**: Laboratory Inquiry
3. Enter Patient’s MRN; SEARCH
4. **Click on**  Microbiology tab
5. Locate bone culture (look around 1 hour before/after time indicated on Tracking Form); record accession number on Tissue Tracking Record
6. Culture reports are finalized about 7 days after collected (Result Status: Final date)
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| **Negative****Culture Result Processing** | **If Negative Culture Result**1. **Culture**: No growth 1 week
2. Enter NEG under Culture Results on spreadsheet
3. Tracking Log: Neg/Pos: Neg -> Cleared from Quarantine: Y
4. Print out Culture Report from SQ Laboratory Inquiry
5. Attach one Tissue ID sticker to Culture Result report & staple report to Tissue Tracking Record
6. Remove green Quarantine form & put bone into regular inventory
7. Put Tissue Tracking Record into appropriate Tissue Tracking binder
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| **Positive****Culture Result Processing** | **If Positive Culture Result**1. **Culture**: *Example: Propionbacterium isolated from broth only*
2. Enter POS under Culture Results on spreadsheet
3. Enter the culture result under Comments
4. **Tracking Log**: Neg/Pos: Pos -> Cleared from Quarantine: N
5. Print out 2 copies of Culture Report from SQ Laboratory Inquiry
6. Attach one Tissue ID sticker on each Culture Result report & staple one report to Tissue Tracking Record
7. Revise Quarantine form: POS Culture & leave bone on the bottom shelf
8. On Tissue Tracking Record write “+Culture, Notification for Release of a Non-Conforming Product form (sent date)” then put back into Tissue Tracking A-L binder under Quarantine section
9. Fill out the Notification of Release of a Non-Conforming Product form and a Notification Letter.
10. Attach copy of Positive Culture Report to form
11. Send thru hospital mail to the corresponding Surgeon

***Note:*** *Harborview Infection Control Policy states that skin flora contamination can be used for re-implantation but bone with more pathogenic organisms will be discarded*. |