[](http://depts.washington.edu/labweb/index.h)

|  |  |  |
| --- | --- | --- |
| **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**

|  |  |  |
| --- | --- | --- |
| **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 |
| 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 |

**Procedure**

|  |  |  |
| --- | --- | --- |
| **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 |  |
| 3. | **Monitor Expiration Dates**   * Monitor bone expiration date for discard. | Discarding Autologous Bone |

|  |  |  |
| --- | --- | --- |
| **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 Record  Notification 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 |  |
| 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 |  |
| 6. | Place Tissue Tracking Record and attached Bone Release form in Issued section of the binder, alphabetically. |  |

|  |  |  |
| --- | --- | --- |
| **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**

|  |  |
| --- | --- |
| **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 |
| **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. |

**Table B: Culture Result Processing**

|  |  |
| --- | --- |
| **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) |
| **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 |
| **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*. |