**Purpose:**

Establish a weekly and monthly review process for identifying and updating bone package status in TSL. Electronic database and paperwork will be maintained and updated throughout the review process.

**Procedure:**

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| **Step** | **Action** | **Related Documents** |
| **Tissue Database** |
| Location | Database is maintained for Autologous Bone packages received in TSL:* Password protected (Main database)
* Access limited to designated staff
* Located on Laboratory Medicine server
* Backed up by Lab Med IT
 |
| Responsibility of | * Designated staff will be trained to maintain the database.
* Password will be shared with TS Manager and QA Specialist.
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| **Weekly**  |
| **Review Autologous Tissue Tracking Log** |
| **All Patients** | * Confirm name, MRN and birthdate on Tissue Tracking Log matches current SQ entry.
* Note any identifier changes and/or discrepancies on the tracking log.
* Request patient demographics update per SOP.
* Attach a copy of investigation and resolution to the Tissue Tracking Record
* Revise cryo label, if necessary
* Update Tissue Tracking Record and Log
* If discrepancy remains unresolved:
	+ Notify TSL Medical Director and Attending Neurosurgeon
	+ Complete a Release of Non-Conforming Bone form
* Complete a QIM and PSN.
 | Autologous Tissue Tracking LogTissue DatabaseUpdating Patient Demographics in Sunquest to Match EPIC Registration ChangesRelease of Non-Conforming Bone |
| **Update Database** |
| **Search** | * Perform Database search by HID number
* **NEW Patient**: Using the Autologous Tissue Tracking Log create NEW patient entry into the Tissue Database.
* **Existing Patients:** Update Database with bone package information
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| **Step** | **Action** | **Related Documents** |
| **Weekly**  |
| **Culture Evaluation and Processing** |
| **Cultured**  | * ***Only when clinically indicated by a surgeon will a culture be obtained.***
* Autologous Tissue Tracking Log will indicate if culture was obtained.
* Enter YES or NO in Database
 |  |
| **Obtain Culture Results from Sunquest** | **Culture Results*** In SQ, search Micro Inquiry using the patient ID/MRN:
* On or before the date of surgery
* Test code WNDANC and WNDF
* *Note: WNDANC is a wound anaerobic culture that should always be performed. WNDF is a fungal culture, not always requested.*
* Click on the boxes to the left of these accession numbers and click on “Get Result” in the bottom right of screen.
* Verify the selected accession number/s is for cranial specimens.
* Update Database:
* Enter Accession number in Tissue Database
* Update Autologous Tissue Tracking Log:
* Record Tech ID in the database entry column
 |  |
| **Negative Cultures** | * Print one culture report
* Apply Tissue ID Number in the top right corner
* Staple the culture result to the back of the Tissue Tracking Record.
 |  |
| **Positive Cultures** | * Print two culture reports
* Apply Tissue ID Numbers in the top right corner of both reports
* Print two copies of a completed Release of a Non-Conforming Autologous Bone form
* Tissue Tracking Record:
* Staple together Non-conforming form, copies of culture result and Tissue Tracking Record.
* File in the Quarantine section of the Tissue Binder
* Medical Director Review:
* Staple Non-conforming form to culture report
* Place in the Medical Director Review box in TSL
* Medical Director Review Completed:
* Outcome of the product determined
* Replace the unsigned copy with the signed/completed copy and file in the appropriate Tissue binder
 | Release of Non-Conforming Autologous Tissue form |

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| **Step** | **Action** | **Related Documents** |
| **Weekly**  |
| **Culture Evaluation and Processing (continued)** |
| **All Cultures** | If the product is deemed unusable:* Proceed to Discard procedure

Move bone package to QUARANTINE bin.If acceptable for Issue:* Place in numerical order (oldest to newest) in the appropriate metal bin
* Record culture result on the Tissue Tracking Log
* Update Database.
* File Tissue Tracking Record in appropriate Tissue binder
 | Discarding Autologous Bone |

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| **Monthly** |
| **Review of Expiring Products** | * Initiate discard process for products expiring within current month.
* Print out a Physicians Letter of Notification and a Discard of Autologous Bone form
* In the Tissue Database under the first notification column:
* Indicate the date sent
* Highlight the row in purple
* Send the letter of notification and discard form to the corresponding physician.
	+ All Neuro Attending mailboxes can be found under the Bone Database folder
* Receipt of signed Discard form:
* Proceed to Discarding Autologous Bone
* Move bone package to QUARANTINE bin.
* If first notification is not received within a month:
* Send a second letter and discard form
* In the Tissue Database under the second notification column:
* Indicate the date sent
* Highlight the row in yellow
* If a second notification is not received within a month
* Forward Discard for Autologous Bone form to Medical Director
* Medical Director review completed, proceed to Discarding Autologous Bone procedure.
 | Physician Notification LetterNotification for Discard of Autologous Tissue FormDiscarding Autologous Bone |

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| **Monthly** |
| **Final Disposition** |
| **Autologous Tissue Tracking Log** | * Review the Autologous Tissue Tracking Log for products that have been:
* Implanted
* Transferred
* Released
* Place a check mark in the Database Entry column indicating the Database was updated
 |  |
| **Database** | * Enter Final Disposition in the Database
* Examples:
* Implanted 9/8/14 @1020
* Transferred UW 8/15/14 @1251
* KCME 10/8/14 @1413
* Highlight the entire row to signify “final disposition”
 |  |
| **Deceased Patient Notification**  | * Review the Deceased Patient Notification forms
* Compare the patient identification with the Autologous Tissue Tracking Log.
* If the patient has a bone package:
* Fill out a Discard of Autologous Bone Form
* Staple to a copy of the Deceased Notification form
* Forward to Medical Director
* Tissue Database:
* Notate “PT Deceased” in the comment column.
* Medical Director Review completed, proceed to Discarding Autologous Bone procedure.
* Move bone package to QUARANTINE bin

***Note: Discard of Autologous Bone will be delayed for a minimum of 2 weeks from the time of death, in lieu of the family’s request for the bone****.* | Notification for Discard of Autologous Tissue FormUpdating Patient Demographics in Sunquest to Match EPIC Registration ChangesDiscarding Autologous Bone |

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| **Semi-Annually and/or Annually** |
| **Tissue Tracking Records** | * Remove Tissue Tracking Records for bone packages that have a final disposition applied **more than 2 years ago**.
* Process for Archived Storage
* In TSL: 2 years
* Off site: 10 years
 | QP: Management of Documents and Records |
| **Tissue Tracking Logs** | * Completed Logs
	+ All entries have a final disposition **more than 2 years ago**
	+ Place in Tissue Tracking Record archive box
	+ Process for Archived Storage
 |