**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 Log  Tissue Database  Updating Patient Demographics in Sunquest to Match EPIC Registration Changes  Release 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 Letter  Notification for Discard of Autologous Tissue Form  Discarding 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 Form  Updating Patient Demographics in Sunquest to Match EPIC Registration Changes  Discarding 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 |