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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: C5004-1** |
| **Revision Effective Date:** | **Pages: 2** |
| TITLE: Storage and Release of Non-Conforming Autologous Bone |

**Purpose:**

To define non-conforming autologous bone and describe the policy and procedure for storage and distribution of non-conforming autologous bone.

**Policy:**

Transfusion Services adheres to current good tissue practices (cGTP) for the acceptance, storage and distribution of autologous bone. These include defining conditions that must be met for a product to be accepted, stored and released. Because these are irreplaceable specimens, under rare circumstances, with the approval of the Medical Director of Transfusion Services and the Attending physician, a product may be accepted, stored, and released when these criteria are not all met provided appropriate documentation is completed.

**Procedure:**

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| **Step** | **Action** | **Related Documents** |
| Evaluate Autologous Bone for Conformity | The Autologous Bone is Non-Conforming if any one of the following applies: * Results of 7 day microbial product cultures are still pending.
* Results of 7 day microbial product cultures are positive.
* Out of temperature monitored freezer storage for longer than 20 minutes with no intent to re-implant at that time.
* Damage to or loss of integrity of the product packaging.
* Issued product was removed from its packing prior to return to the TSL.
* Failure of the temperature monitored freezer in which the autologous bone is stored.
* Tissue exceeds the 24 month storage limit
* Product is received back into TSL after release and transport to outside facility.
 | * Receipt of Autologous Bone for Re-implantation
* Maintaining and Issuing Autologous Bone for Re-implantation
* Autologous Bone Tracking Log
* Tissue Tracking Record
* Bone Release form
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| Complete Notifications and Quarantine bone package | * Place the package in Quarantine per SOP.
* Fill out a “Notification for Release of Autologous Bone from a Non-Conforming Product Form” and Notification Letter.
* Forward for signature to the Attending Physician
* Subsequent to Attending Physician completion of the form, forward to the Transfusion Service Medical Director

***NOTE:*** The form must be completed and signed by the Attending physician and the Transfusion Service Medical Director prior to release of any Non-conforming Bone. | * Receipt of Autologous Bone for Re-implantation
* Notification for Release of a Non-Conforming Autologous Bone form
* Autologous Bone Tracking Log
* Notification Letter
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| Once the Non-Conforming Product Form has been signed | * Staple the completed form to the Tissue Tracking Record
* Maintain the non-conforming bone package in the appropriate storage area of the -80C freezer
* Release the Non-Conforming product per SOP
 | * Maintaining and Issuing Autologous Bone for Re-implantation
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| If directed to discard the Non Conforming Product | * Complete notification to discard form
* Forward to TSL Manager/Medical Director for Signature
* Once the completed and signed Discard Form is received back in TSL, discard the Non Conforming Product per SOP
 | * Discarding Autologous Bone
* Notification of Discard of Bone form
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**References**

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