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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:**September 2, 2013 | **Number: C5007-1** |
| **Revision Effective Date:** | **Pages: 3** |
| TITLE: Storage and Release of Non-Conforming Autologous Cranial Bone Flaps.  |

**Purpose:**

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

**Policy:**

Transfusion Services adheres to current good tissue practices (cGTP) for the acceptance, storage and distribution of autologous cranial bone flaps. 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, Medical Director of Neurosurgery (or designee), and the patient’s 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** | **Responsible Entity** | **Action** | **Related Documents** |
| * Determine if the Autologous Cranial Bone Flap is a Non-Conforming Product.
 | * TSL Staff
 | The Autologous Cranial Bone Flap is Non-Conforming if: * The product is to be released prior to completion of microbial cultures
	+ - * *OR*
* It is removed from temperature monitored freezer storage for longer than 20 minutes with no intent to re-implant at that time.
 | * Receiving Autologous Bone Flaps into Storage for Re-implantation
* Performing Visual Inspection of Autologous Cranial Bone Flap Package
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| **Step** | **Responsible Entity** | **Action** | **Related Documents** |
| * Determine if the Autologous Cranial Bone Flap is a Non-Conforming Product

(*Continued)*. | * TSL Staff
 | The Autologous Cranial Bone Flap is Non-Conforming if: * There is damage to or loss of integrity of the product packaging.
	+ - * *OR*
* An issued product was removed from its packing prior to return to the TSL.
	+ - * *OR*
* There is failure of the temperature monitored freezer in which the autologous bone is stored.
	+ - * *OR*
* The tissue exceeds the 24 month storage limit
	+ - * *OR*
* Product is received back into TSL after release and transport to outside facility, but was not used.
 | * Storing and Tracking Autologous Cranial Bone Flaps for Re-implantation
* Autologous Cranial Bone Flap Tracking Log Form
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| * If the patient’s physician is requesting that a non-conforming autologous bone “flap” be accepted for storage or release
 | * TSL Staff
 | * Notify the Medical Director of Transfusion Services/Transfusion Services Resident to determine whether to accept the product
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| * If you are directed to place accept and store or release the autologous cranial bone flap by the Transfusion Services Medical Director/Resident
 | * TSL Staff
 | * Follow steps in the Storing and Tracking Autologous Cranial Bone Flaps for Re-implantation SOP
* Fill out a “Notification for Use/Release of Autologous Cranial Bone from a Non-Conforming Product Form.”
* Forward “Notification for Use/Release of Autologous Cranial Bone from a Non-Conforming Product Form” to Neurosurgery & the Transfusion Service Manager/Medical Director for signature
* ***NOTE:*** The form must be completed and signed by the Director of Neurosurgery (or Designee), patient’s physician and the Director of the Transfusion Service prior to release of any Non-conforming Cranial Bone Flap.
 | * Storing and Tracking Autologous Cranial Bone Flaps for Re-implantation
* Autologous Cranial Bone Flap Tracking Log Form
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| **Step** | **Responsible Entity** | **Action** | **Related Documents** |
| * Once the Non-Conforming Product Form” has been signed
 | * TSL Staff
 | * Release the Non-Conforming product per SOP
 | * Releasing Autologous Cranial Bone Flaps
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| * If directed to discard the Non Conforming Product
 | * TSL Staff
 | * 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 Cranial Bone Flaps
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**References**

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