University Hospitals of Morecambe Bay NHS Foundation Trust

Document Type: **Procedure**	**Unique Identifier:** SURG/LOCSSIP/001
Document Title: **Local Safety Standard for Invasive Procedures (LocSsip) for:** **The Procurement and Use of Skeletal Allografts, e.g. Fresh Frozen Femoral Heads**	**Version Number:** 1 **Status:** Ratified
Scope: Any member from the Theatre MDT who order, store and undertake completion and the return of traceability documentation of all allografts that are implanted into patients at UHMB that have been provided by NHSBT	**Classification:** Departmental
Author / Title: Sue Wroe, Governance Project Lead NATSSIP's Quality & Governance	**Responsibility:** Surgery
Replaces: N/A	**Head of Department:** Michael Thompson, X Bay Theatre Manager
Validated By: Divisional Procedural Document Group Divisional Governance and Assurance Group	**Date:** 10/02/2016 23/02/2016
Ratified By: Procedural Documents and Information Leaflet Group Chairman's Action	**Date:** 29/03/2016
Review dates may alter if any significant changes are made	**Review Date:** 01/02/2019

Which Principles of the NHS Constitution Apply? **Please list from principles 1-7 which apply** 1,2,3,4,6 Principles	**Which Staff Pledges of the NHS Constitution Apply?** **Please list from staff pledges 1-7 which apply** 2,5 Staff Pledges

Does this document meet the requirements of the Equality Act 2010 in relation to Race, Religion and Belief, Age, Disability, Gender, Sexual Orientation, Gender Identity, Pregnancy & Maternity, Marriage and Civil Partnership, Carers, Human Rights and Social Economic Deprivation discrimination? **Yes**

Document for Public Display: No

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1. SUMMARY

Musculoskeletal Allografts include a broad range of human tissues including bone, tendons, cartilage and ligaments.

It is a requirement of the European Union Tissue and Cells Directive (EUTCD) that tissues are tracked from donor to recipient. Tissue Services, which is part of NHS Blood & Transplant service, use the same computerised tracking system that is used to track blood donations - 'PULSE'. This system facilitates an electronic audit trail from donor to dispatch. Allografts from National Health Service Blood & Transplant (NHSBT) Tissue Services are labelled using the ISBT 128 labelling standard barcode format. This is described and defined in the Guidelines for the Blood Transfusion services in the UK chapter 26.

The Surgical Operating Team at UHMB are required to complete the audit trail from tissue receipt to patient or discard, and this requirement is included in the Service Level Agreement (SLA) that all users must sign up to before tissue can be supplied. The EUTCD requires that the tracking method is documented in end users Standard Operating Procedures, and are summarised for the staff of UHMB in this Standard Operating Procedure.

2. PURPOSE

The purpose of this Standard Operating Procedure is:
To ensure that all stakeholders understand and comply with the obligatory NHSBT regulatory standards of traceability which are required to be followed for each allografts used.

- By ensuring the documentation of ISBT 128 system, that is used for this purpose is completed, filed and or logged into the patient's notes, and the applicable sections returned to NHSBT Tissue Services in all cases when any allograft is implanted.
- By ensure that any received allograft is verified as being the correct allograft for the planned procedure and patient it was ordered for.

3. SCOPE

This Standard Operating Procedure is applicable to all staff in the theatre MDT.
The robust adherence to both the regulatory standards required for traceability and the safe standards of this operating procedure must be followed by all staff who facilitate, or participate in any aspect of regulatory processes relating to implantation of allografts, e.g. ordering, receiving, safe storage, the completion of traceability documentation, and, if applicable, the return of any suitable **unused** allograft to NHSBT.

Any untoward events or errors should be escalated and actioned accordingly and reported for investigation on the Trusts Patient Safety Module (Safeguard) by the raising of a Clinical Incident Report (CIR)
NHSBT, the issuing Tissue Bank, must also be notified of the incident and actions agreed.

4. STANDARD OPERATING PROCEDURE

4.1 Ordering of Allografts

Allografts can only be ordered from tissues banks that meet the regulatory requirements of the Human Tissue Act and are licensed by the HTA (Human Tissue Authority)
A current service level agreement (SLA) should be in place and reviewed by the theatre manager/matron in accordance with the SLA expiry dates.

UHMB requires that the Clinical Leader or deputy in charge of the theatre requiring / using the allograft is accountable for ensuring that the ordering, storage, regulatory tracking and traceability documentation is completed, processed and dispatched in accordance with the requirements of the service level agreement from the issuing Tissue Bank and standards of patient documentation at UHMB.

- Telephone NHS Blood & Tissue Transplant National Orderline **08456076820**.
- Inform customer services at NHSBT Tissue bank of the allograft type and purpose of use.
- Ensure the appropriate transport & storage container is confirmed at the time of order.
- **N.B** When ordering a **Fresh Frozen Femoral Head/s** ensure the specialist **48-hour storage container** is requested and confirmed. (Additional charge). Upon receipt and up until use this must remain unopened with integrity intact, as this preserves the allograft for a 48-hour period, thus allowing for return to NHSBT Tissue Bank if for any reason it is not opened or required for the specific surgical procedure. (See 4.7).
- Provide the surgeons name, patient's RTX number, delivery date required and the precise location for delivery, stating clearly which hospital theatre suite and site.
- The staff member who has placed the order over the phone must use their Trust email address as the point of contact.
- Response from NHSBT is instant by email to the orders email address and this allows for the check by the requisitioning staff member.
- Information of the order placed with NHSBT must immediately be documented in the theatre communication book.
  The information must include:

  - Patient name & RTX number for whom the allograft has been ordered
  - The type of allograft
  - Operating consultant and planned date of operation.

4.2 Delivery/ Receipt and Storage of Allografts in Theatres

- The ordered allograft will arrive by NHSBT own transportation or a nominated courier to the Theatre Reception.
- A trained staff member must receive and sign the allograft into the department.
- Under no circumstances should the seals of the transport box be broken, it is vital that the integrity of the transport box and the inner box remains intact.

- After signing for the delivery, immediately take the unopened box to the orthopaedic theatre.
- Receipt of the correct allograft must be confirmed.
- Ensure that the documents enclosed in the outer packaging wallet match the details of the order placed which has been recorded in the orthopaedic theatre communication book.
- If all is correct, you must record the receipt in the theatre communication book, alongside the information relating to the order.
- Inform the team leader the allograft has arrived, (If the allograft arrives out of hours in the absence of the Orthopaedic team leader inform the theatre coordinator and complete the theatre specific communication book).
- If you have any queries or concerns that the allograft is not correct it must be escalated at this time.
- The Theatre Coordinator must communicate the receipt and whereabouts of the allograft at handover to the team leader/deputy when next on duty.
- At all times the box must remain intact, it will only be opened during the surgical procedure when the operating surgeon confirms he is ready for the graft.

4.3 Opening the Allograft for Implantation

- It is the responsibility of any staff member who may handle allograft transport boxes to ensure that they have read and understood the COSH Risk Assessment **http://uhmb/cd/Governance/COSHH/Pages/default.aspx** prior to undertaking any tasks associated with it.
- The box containing the allograft must never be opened in a non-ventilated confined space. The area in which it is opened must always have a ceiling vent present, and where possible the box must be placed underneath it.
- Place the box containing the allograft below an air vent either in the operating theatre or theatre setting up room where the surgery on the recipient is taking place.
- Break the outer seal of the allograft transport box, (Inside this box is an inner pot stored in dry ice CO_2 Crystals)

4.3.1 Safety instructions for handling the allograft for implantation

- Before removing the lid of this box you must make sure you are wearing eye protection, this may be goggles or a visor.
- Before inserting your hands inside this box to remove the inner box you must ensure you are wearing the thermo protection gloves that are supplied for your protection.
- Place the inner box safely on a flat surface, and then proceed to reattach the lid to the outer box containing the dry ice to avoid a workplace accident, it may be necessary to apply securing tape.
- when undertaking the next step, any PPE may be removed. However, if the inner pot feels too cold to handle for the individuals comfort, then it must be held by wearing the thermos gloves. In this instance a 2ND person may be required to assist in opening the inner pot.
- When the inner box is open pass the allograft to the scrub practitioner to theatre aseptic technique standards.
- Complete documentation standards as defined in section 4.5 of this SOP.

4.4 Completion of Implantation Documentation

- Using black pen complete the traceability documentation provided. This documentation must be returned to NHSBT in the internal post from the department.
- Input the details relating to the used allograft into the Operating Room Management Information System (ORMIS) as an implant, including the unique identification number and expiry date as supplied by NHSBT.
- Using black pen, record the details in the book held in theatre which is specifically identified as the 'NHS blood & tissue transplant book' using the bar-coded stickers supplied, along with recording the date and attach a patient identification sticker.
- In black pen you must also record a copy of the donation or batch number and allograft code in the patient's medical notes so that should an event occur possibly attributable to the tissue graft then the implicated unit can be quickly identified. (This could be a photocopy of the allograft labels themselves to minimise transcription errors).

4.5 Returning Unused, Unopened Allografts to the Tissue Bank at NHSBT

- If returning an unused allograft, call NHSBT customer service on 08456076820 to arrange the collection.
- You will be asked to provide details of the graft number and date of packing.
- The allograft must not be more than 48 hours old from the date and time of dispatch from NHSBT and have remained unopened to be eligible for return to NHSBT in Liverpool. The information relating to NHSBT issue dates and time can be found on the external packaging.
- Provide the exact location where the allograft for return can be collected from.
- Ensure that the returns label from the document wallet is completed and attached securely for the return of the allograft.
- Ensure the return is documented on any order paperwork for the audit trail.

5. ATTACHMENTS	
Number	**Title**
1	Example of label and tracing log used by HSBT
2	Equality and Diversity Impact Assessment

6. OTHER RELEVANT / ASSOCIATED DOCUMENTS	
Unique Identifier	**Title and web links from the document library**
I5	Clinical Guideline for Transmissible Spongiform Encephalopathies http://uhmb/cs/tpdl/Documents/I5.pdf

7. SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS **References in full**	
Number	**References**
1	The Human Tissue (Quality and Safety for Human Application) Regulations 2007
2	NHS Blood and Transport (NHSBT)
3	European Union Tissues and Cells Directives
4	N.M.C. Standards of Recording Keeping 2009
5	Guidelines for the Blood Transfusion services in the UK chapter 26

8. DEFINITIONS / GLOSSARY OF TERMS	
Abbreviation or Term	**Definition**
Allograft	Tissue obtained from a separate donor that has been procured and tested for implantation by a regulated supplier i.e. NHSBT Bone & Tissue Bank
NHSBT	National Health Service Blood and Transplant.
UHMB	University Hospital Morecambe Bay
MBHT	Morecambe Bay Hospital Trust
SLA	Service Level Agreement
HTA	Human Tissue Authority
EU	European Union
EUTCD	European Union Tissue and Cells Directive
P.U.L.S.E	Name given to the computer system at NHS blood and transplant
O.R.M.I.S.	Operating room management information system
ISBT 128	International Standard Blood & Tissues labelling system
NatSsips	National Safety Standards Invasive Procedures
LocSsips	Local Safety Standards Invasive Procedures

9. CONSULTATION WITH STAFF AND PATIENTS Enter the names and job titles of staff and stakeholders that have contributed to the document	
Name	**Job Title**
Sarah Cullen	Assistant Chief Nurse Surgery & Critical Care
Faye Bennett	Clinical Leader RLI Orthopaedic Theatre
Daniel Bakey	Cross Bay Theatre Matron

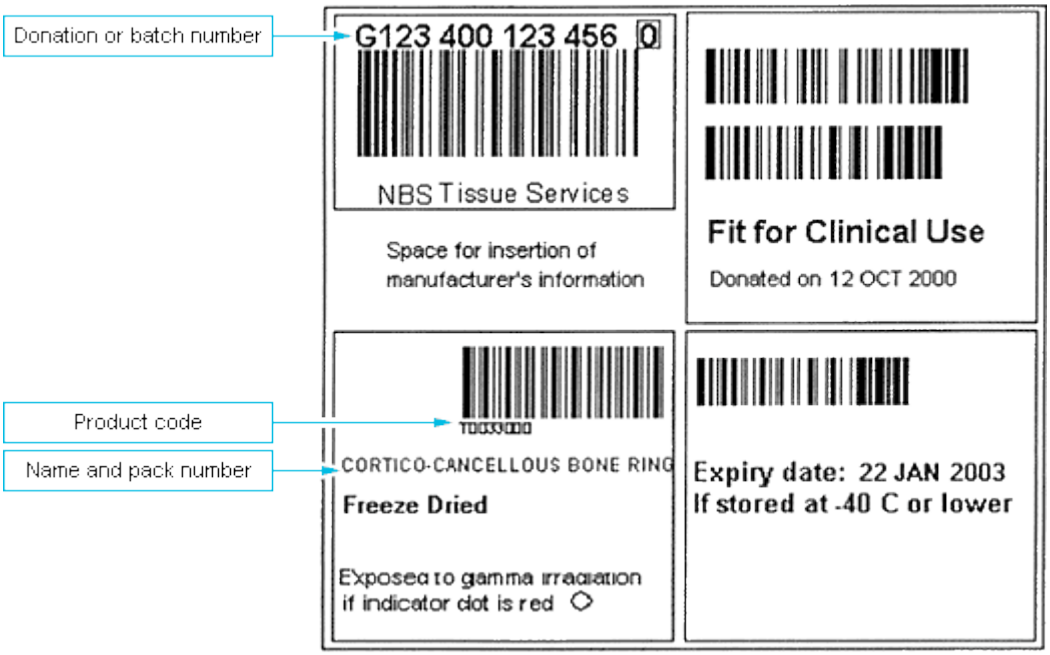
10. DISTRIBUTION PLAN	
Dissemination lead:	Daniel Bakey X Bay Matron Theatres
Previous document already being used?	No
If yes, in what format and where?	N/A
Proposed action to retrieve out-of-date copies of the document:	N/A
To be disseminated to:	Clinicians Orthopaedics All Band 7's Theatres Clinical Leaders Orthopaedic Theatres X Bay Theatre Management Group for noting. DGAG for noting
Document Library	SharePoint
Proposed actions to communicate the document contents to staff:	Disseminate communication and the link for the validated LocSsip when loaded

10. DISTRIBUTION PLAN	
	onto Trust system, to key theatre staff / lead clinicians Divisional Governance Assurance Group (DGAG) for noting when approved by Procedural group Include in division newsletter.

11. TRAINING Is training required to be given due to the introduction of this policy? No		
Action by	**Action required**	**Implementation Date**

12. AMENDMENT HISTORY				
Revision No.	**Date of Issue**	**Page/Selection Changed**	**Description of Change**	**Review Date**

Appendix 1: Example of label and tracing log used by HSBT



Example of tissue tracking log which can also be used as an inventory. The fields below should be mandatory information

			Fate				
			Discard date and by whom	Recipient/Patient			
Donation or Batch number	Allograft code	Date received		Name	DOB	Hospital Number	Date and surgeon

Appendix 2: EQUALITY & DIVERSITY IMPACT ASSESSMENT TOOL

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Age	No	
	• Disability	No	
	• Race	No	
	• Sex	No	
	• Religious belief – including no belief	No	
	• Sexual Orientation	No	
	• Gender reassignment	No	
	• Marriage and civil partnership	No	
	• Pregnancy and maternity	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination are there any exceptions - valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
4a	**If so can the impact be avoided?**	No	
4b	**What alternative are there to achieving the policy/guidance without the impact?**	No	
4c	**Can we reduce the impact by taking different action?**	No	

For advice in respect of answering the above questions, and / or if you have identified a potential discriminatory impact of this procedural document, please contact the relevant person (see below), together with any suggestions as to the action required to avoid/reduce this impact.

For Service related procedural documents: Lynne Wyre, Deputy Chief Nurse & Lead for Service Inclusion and Diversity

For Workforce related procedural documents: Karmini McCann, Workforce Business Partner & Lead for Workforce Inclusion and Diversity.