Mid Essex Hospital Services NHS
NHS Trust

Epidermal Allograft – Standard Operating Procedures	**Policy** **Register No: 07005** **Status: Public**

Developed in response to:	Human Tissue Authority Licence Application Improved communication and support for staff involved in handling tissue for human application.
Contributes to CQC Outcome number:	4

Consulted With	**Post/Committee/Group**	**Date**
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Professionally Approved By Professor Dziewulski	Clinical Director St Andrews Burns and Plastics	April 2015

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Document Review History

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1. Purpose

1.1 The Trust is committed to providing high quality patient care and a safe environment for all its users (patients, members of staff, and members of the public).

1.2 The purpose of this document is to give guidance to all staff and in particular those involved in the handling of tissue for Human Application.

2. Scope

2.1 This policy applies to all Staff employed by the Trust on a substantive and temporary basis involved in the handling of tissue for Human Application.

2.2 This Policy applies specifically to patients both adults and children who require the application of Epidermal Allograft.

3. Staffing & Training

3.1 All staff involved in the handling of tissue for Human Application will receive training at local induction. Other competencies, training and updates will be arranged as required through line managers and in conjunction with the Tissue Storage Co-Ordinator.

4. Definitions

4.1 Allograft is tissue that is taken from one person's body and grafted to another person.

4.2 Autograft is tissue that is taken from one part of a person's body and transplanted to a different part of the same person.

5. Freezer Facilities

5.1 The tissue facilities consist of one ultra low temperature freezer in Burns ITU maintaining a temperature of between –81^{o}C and -84^{o}C

6. Documentation relating to Storage

6.1 Master copies of all Epidermal Allograft Storage documentation will be held in a locked filing cabinet in Broomfield Burns Service under the control of the designated allograft storage coordinator or the deputy allograft storage coordinator.

6.2 All documentation relating to epidermal allograft storage will be reviewed annually unless changes in practice or guidelines from the Department of Health, Human Tissue Authority, NHS Blood and Transplant service require such review to occur earlier.

6.3 Reviewed documentation will only be circulated after being approved by the Clinical Director, the designated allograft storage coordinator, the deputy allograft storage coordinator and after consulting other parties who may be affected by any proposed changes.

6.4 Approved copies of documents reviewed will be made available to all Burns and Plastic Surgery Consultants, the burns service and plastics wards, the Theatre Manager and the theatre and ward staff as necessary. Copies will be placed in the burns and plastics theatres at Broomfield Hospital for reference.

6.5 A list will be kept in the Burn Service of everyone who receives a copy of allograft storage documentation so that obsolete documentation can be traced and destroyed

6.6 The allograft storage coordinator or the deputy will notify staff when documentation is superceded. If documentation is reviewed and no changes are made this recall will not be undertaken

6.7 A copy of documentation issued by the Allograft storage co-ordinator will be kept (stored in a locked cabinet within the Burns Unit) for a minimum of eight years.

7. Documentation relating to Patients

7.1 All documentation shall be completed in permanent ink

7.2 All patient recordings will be stored in a locked cabinet within the Burn Service. Access will be limited to

- the clinical director
- the microbiological advisor
- allograft storage coordinator
- deputy allograft storage coordinator
- access to records staff

7.3 The allograft storage coordinator or deputy allograft coordinator are responsible for monitoring that documentation is completed correctly. Where this is not the case they will trace the staff responsible to rectify any problems and provide additional training as deemed necessary.

7.4 All Patient recordings relating to Allograft shall be retained for 30 years. (All records retention must comply with Appendix D1 the Health Records Retention Schedule to the NHS Records Code of Practice).

7.5 Each Allograft packet has a unique identifiable code. This is the number on the pre-printed label supplied by the tissue bank at time of issue. This will allow each unit of donation to be traced whilst maintaining the donor's confidentiality.

7.6 This label must be attached to allograft register against recipient information at the time of surgery. A photocopy of which should be inserted into the correspondence section of the patient's notes. In order that the Trust will be able to meet its responsibilities to supply all records held by the Trust, it will be necessary to affix an Alert (see inside front cover) sticker to the front of the notes and write in the boxes on the inside, the reference numbers of the documentation held in Burns of the allograft event in order that these can be readily accessed by the Access to Records Bureau.

8. Allograft Disposal

8.1 There will be instances where viable allograft taken from the allograft freezer will need to be discarded. Such instances will include, but these examples are not exhaustive.:

- Allograft that remains unused after the 2 year expiry date
- Damage to containers sufficient to pose a risk to content sterility or if there is evidence of tampering
- Failure of the allograft freezer to maintain temperature within the range of -75^{o}C to -82^{o}C where no suitable alternative can be located before the internal temperature rises above -40^{o}C
- It is not permitted to store post operatively, Allograft released from the allograft freezer. Where Allograft has been released for use, and has either been opened or remains at room temperature for longer than 30 minutes and is not required for a planned patient procedure disposal procedures should be followed.
- Failure to adhere to the Epidermal Allograft Storage Standard Operating Procedures

8.2 Allograft will be disposed of as Anatomical Waste adhering to the following Guidelines:

- To prevent cold related injuries Thermal protective gloves must be worn. If defrosted, allograft is to be disposed of using disposable gloves.
- A disposable plastic apron and eye protection should also be worn
- If the allograft is still in its containers these will be placed into a Trust approved Bio Bin
- If the allograft is not in a container it will be placed directly into a Trust approved Bio Bin
- The disposable gloves and apron will be discarded within the clinical waste bag. The bags are then to be tied and sealed with a bag tie.

9. Documentation Relating to Allograft Disposal

9.1 The person discarding allograft must complete a Disposal Form (Appendix A). This must be completed for all instances where allograft is not used but is otherwise discarded

9.2 All documentation relating to the disposal must be retained within the Burns Service

9.3 If the Allograft freezer breaks down and no suitable alternative can be located for the internal temperature rises above -40^{o}C all the freezer contents will be discarded

9.4 Allograft that is released from the tissue bank or the allograft freezer for use will not be returned to the freezer if either the containers or packets are opened or if it remains at room temperature for longer than 30 minutes. However, this may be stored aseptically in a medical grade refrigerator on a named patient basis as non-viable allograft for 24 hours past thawing/ dilution.

10. Procedure for Ordering – Allograft

10.1 If the stock level declines, stock needs to be ordered via the Non Stock Requisition book.

10.2 Determine what quantities of the product is required – (liaise with Consultant Surgeon in charge of patient recipient case).

10.3 Establish quantities currently held within the service.

10.4 Contact the Head of Nursing on Ext 3690 or bleep #6400252 or Lead Nurse for Burns Service Ext 6037 to advise of your actions. Have all details available – patient information, when product is required and how much of the product is currently available on site.

10.5 To place an Allograft order contact

Tissue Bank Services, Liverpool – 0151 5527078

10.6 To proceed with the order, Tissue Services will require the following information:

- Quantity of Allograft needed
- When the order needs to be delivered
- For which patient the Allograft is being order (you will require the patient's hospital number)
- Which Consultant Surgeon is to be named on the order

10.7 The Requisition book must be signed by Lead Nurse Burns Service if cost is under £25,000 or Head of Nursing if cost is above £25,000. On receipt of signed requisition, Procurement EXT 6474 quoting the relevant requisition book number.

10.8 You will be issued with the ME000 number. Phone Liverpool Tissue Services with this number and ask them to email or fax Burns ITU (01245 516171).

10.9 Liverpool Tissue Services will despatch Allograft at agreed delivery time.

10.10 Send requisition form to Procurement via internal post.

11. Out of hours – Ordering of Allograft

11.1 An out of hours ordering service for allograft is available via an ON CALL TISSUE BANK TECHNICIAN whose contact details are provided by an Out of Hours Answer Phone Service (Tel: 0845 607 6820).

11.2 However, it is important to note that allograft is usually not needed immediately on patient admission. Providing the need for usage is established initially, the Skin Bank will courier the product within 4-24 hours if sufficient stock is held by the

Tissue Bank and the ORDERING Process outlined above has been followed. Out of hours, approval to order the product must be obtained from the Executive Director on Call, via the Manager on Call. The Manager on Call will confirm this request and approval by e-mail to the Lead Nurse for Burns. (Same day delivery will incur a delivery charge).

12. Monitoring of Cryopreserved Epidermal Allograft Freezer

12.1 The cryopreserved epidermal allograft freezer is located in Research Lab 1, Burns ITU.

12.2 During the hours of 8am to 6pm Monday to Friday it is the responsibility of the theatre staff to undertake the monitoring and recording. At all other times, including weekends it is the responsibility of burns ITU staff to monitor and record the temperature of the allograft freezer.

12.3 It is the responsibility of the nurse in charge of either burns theatre or burns ITU to ensure this task is carried out.

12.4 The freezer should be monitored and temperature recorded twice daily in the temperature log – located on the work surface above allograft freezer.

12.5 Monitoring should take place before 12 midday and 12 midnight.

13. Action to take in the Event of Freezer Failure

13.1 The freezer alarm will sound and the senior member of staff on duty should be notified. (If the alarm is activated due to a fault, the Allograft freezer door must remain closed until an engineer has rectified this. The engineer will be contacted by the senior nurse on-duty within the Burns Service).

13.2 The senior member of staff on duty will contact the Contracted Service Provider to arrange earliest possible call-out for repair.

13.3 If the call out time exceeds 24 hours steps must be taken to transfer freezer contents.

13.4 The senior member of staff on duty will contact the key holder for the alternate freezer, housed in Broomfield Main Orthopaedic Theatres, in order to arrange transfer.

13.5 In the event of failure and the need to transfer tissue, allograft freezer key must be obtained.

13.6 Transfer must take place by placing allograft packs within polystyrene transport boxes, located in Research Lab 1. Tissue packs should be packed with cold blocks stored within the fridge in Burns Theatre. Transport boxes should be taped and sealed to secure them, date and time of transfer to be attached to transport boxes together with signature of senior member of staff.

13.8 Transferred tissue will be reassessed for further use by the Consultant Burn Surgeon and theatre staff advised accordingly.

14. Routine Management of the Freezers

14.1 The tissue facilities consist of a freezer maintaining a temperature of between -80^{o}C and -84^{o}C. This must be maintained at all times.

14.2 If the temperature rises above -40 degrees centigrade the allograph will have to be discarded following consultation with the clinical director

14.3 The freezer temperature is recorded manually twice daily

14.4 This data, along with previous records of Allograft freezer temperature, will be kept in accordance with Annex D1, the Health Records Retention Schedule appendixed to the NHS Code of Practice on Records Management.

14.6 Annual maintenance will be performed according to the agreed service contract.

14.7 Annual calibration of temperature monitoring devices will be performed

14.8 There is an alarm system in operation at all times to alert attention if the temperature rises.

14.9 The Allograft freezer must be connected to the maintained electricity supply.

14.11 **Checking the System**
If the alarm is activated due to a fault, the Allograft freezer door must remain closed until an engineer has rectified this. The engineer will be contacted by the senior nurse on-duty within the Burn Service.

14.12 **Out of Hours Alarm Activation**
If the alarm is activated out of normal working hours or at the weekend, it is the responsibility of the Senior ITU Nurse to contact the Theatre Sister promptly. The Theatre Sister on-call will contact the on-site engineers. If they are unable to rectify the problem then the company that services the Allograft freezer must be contacted.

15. Breaches

15.1 Any occurrences of freezer failure must be recorded on a risk event form (Datix)

15.2 Any incidence of non-compliance with this policy that results in any patient harm ie delays to treatment, must also be recorded on Datix.

16. Audit & Monitoring

16.1 An Audit Report of the Allograft Storage activities will be submitted to the Clinical Director on a quarterly meeting basis which will be documented and kept in the HTA Quality Manual

16.2 An internal review, which will include consideration of all reported risk events and complaints will be carried out twice a year and submitted to the Clinical Director.

17. Implementation & Communication

17.1 It is a corporate responsibility to ensure that this policy is uploaded to the intranet and website and notified to staff in Focus.

17.2 It is the author's responsibility to issue a personal copy by email to all staff directly involved with the purchase, use or disposal of Allograft.

18. Reporting a Serious adverse Event (SAE) or Serious Adverse Reaction (SAR).

18.1 Any Serious Adverse Event or Reaction relating to the use of Epidermal Allograft must be reported to the Human Tissue Authority and Datixed. The classifications for this are as follows:

- an untoward occurrence associated with the procurement testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling, or incapacitating conditions for patients or which might result in, or prolong, hospitalisation.'(HTA 2004)

- an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating, or which results in, or prolongs hospitalisation or morbidity. (HTA 2004)

18.2 An SAE\ SAR can be reported via the Human Tissue Authority portal, these events can only be reported by the Designated Individual(DI), who is Professor Peter Dziewulski. In the DI's absence this responsibility can be delegated to other designated members of staff.

18.3 An SAE or SAR must be reported as soon as possible after the incident has been discovered.

18.4 A datix report must also be submitted as soon as possible after the incident has been discovered. A drop down box on the datix form is available with the heading of HTA, this should be chosen.

19. Termination of Epidermal Allograft Usage

19.1 In the event that Epidermal Allograft is no longer required for use or not stored within the hospital, guidelines are in place to facilitate this process.

19.2 If staff know in advance that Epidermal Allograft is no longer to be used or stored within the hospital then the stock level can be reduced by using all current Epidermal Allograft and not ordering any more.

19.3 Any retained stock could be transferred to another hospital who hold an appropriate Licence. The most suitable choice for this would be to store any unused Allograft under the licence held for the Orthopaedic Theatres. This is the held under the umbrella of Leister Bone Bank. Alternatively, any unused Allograft could be returned to Liverpool Tissue Services.

19.4 All records and paperwork relating to Epidermal Allograft must be stored for 30 Years and must therefore be transferred to another establishment which holds An HTA licence.

19.5 All paperwork relating to the above can be held in Broomfield Orthopaedic Theatres, who operate under Leicester Bone Bank's Licence.

20. References

HTA 2004

Appendix A

Epidermal Allograft Disposal Record

This section to be completed at time of disposal

Allograft Bank Donor Number:		
Thawed/Dilluted in name of patient (surname/first name)	Consultant:	
Hospital Number:	Date of Birth:	Operation Date:

Reason for disposal (circle code where appropriate providing specific details under comments):

Reason for disposal	Code	Comments
Allograft unsterile		
Packaging damaged	1a	
Mishandling	1b	
Other	1c	
Infection risk		
Tissue storage limit exceeded	4a	
Administrative		
Incorrect consent	5a	
Incomplete donor questionnaire	5b	
Incomplete Allograft bank documentation	5c	
Other	5d	
Allograft opened in error		
Not required	6a	
Wrong blood group	6b	
Freezer Failure	7a	
Allograft removed from freezer for 30 minutes	8a	
Other	9a	

For Allograft Bank use only:
Comments including any action required:

Allograft disposed of by:

Print name

Signature