Inspection report on compliance with HTA licensing standards
Site visit date: **13 October 2021**
Virtual Regulatory Assessment (VRA) date: **5 November 2021**

Sunderland Royal Hospital

HTA licensing number 22610

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

Licensed activities

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Sunderland Royal Hospital	E*			E			

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone				Authorised			

Musculoskeletal, Cartilage; Cartilage (ATMP)	Authorised*						
Musculoskeletal, Tendon & Ligament; Tendons				Authorised			

Summary of inspection findings

The HTA found that Sunderland Royal Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection. However, four major and seven minor shortfalls were found against standards for Governance and Quality, Premises, Facilities and Equipment, and Disposal. The HTA is concerned about the recurrent nature of the shortfalls that were identified.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, but will monitor the actions taken to address the shortfalls identified during this inspection in order to reach a decision on whether further action is needed.

Compliance with HTA standards

Major shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	A central department orders allografts. There is no documented procedure setting out that the temperature range of the freezer in which the allografts are stored must be provided to the supplier. This information is used to assign the correct expiry date to the allograft [see shortfall against standard PFE3c and PFE3d]. There is no documented procedure describing what to do if an allograft is removed from the freezer but not required for use. Establishment staff confirmed allografts should not be returned to the freezer once removed. However, during the review of traceability records, a handwritten note was observed in the record book stating an allograft was removed from the freezer and subsequently returned. The incorrect temperature for the allograft storage freezer is stated in the standard operating procedure (SOP) for allograft receipt, transfer, storage, use and disposal.	**Major**

GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	There has been no independent audit carried out to verify compliance with the relevant HTA standards. This was a finding in the previous two inspections. Previously, the shortfall was closed based on a planned schedule of independent audits. However, workforce pressures due to the emergence of COVID-19 meant this schedule was not implemented. At the time of the inspection, no further progress had been made with implementing the schedule.	**Major**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes. b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells. c) Staff can access risk assessments and are made aware of local hazards at training.	Risk assessments for practices, processes and the premises were not available for review during the inspection or prior to the finalisation of this report. It was indicated these were held by a central department within the Trust and were requested, but no documents were made available. A shortfall relating to risk assessment review was identified during the previous inspection. The corrective action was the addition of appropriate review dates. The establishment notified the HTA that this action had been taken; however this could not be confirmed during this inspection as the documents were not made available to the HTA.	**Major (cumulative)**
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.		

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity. d) There is a documented, specified maximum storage period for tissues and / or cells.	The establishment stores allografts in a freezer with minimum and maximum alert limits set at -35°C and -25°C respectively. Information available from the allograft supplier states allografts stored at temperatures greater than -40°C have a revised (shortened) expiry date. Establishment staff confirmed they have received allografts labelled with the incorrect expiry date for the freezer storage temperature range used [see shortfall against standard GQ1b]. During the review of traceability records, one incidence was identified in which an allograft was used approximately one month after the actual expiry date for the product.	**Major**

Minor shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.	The document 'Policy for the use of Bone Products and Storage' previously used in the department in which the freezer is located is obsolete but still referenced in the document control system. The Designated Individual (DI) was advised in the previous inspection to distribute the appropriate SOP to the department, but this has not been done.	**Minor**

GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	There is no quality manual which provides an overview of the quality system.	**Minor**
b) There is an internal audit system for all licensable activities.	An audit of freezer temperature records was not completed during the allograft audit, as required by the establishment's documented procedure.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Porters collect allografts from the freezer when requested to do so by Theatre staff. There is no formal training programme including a record of competence for Porters carrying out this task.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.	The establishment maintains a record book to track the receipt, storage and use or disposal of allografts purchased from another HTA-licensed establishment. The SOP states that details of allograft(s) used in a patient must be recorded in the computerised theatre record (also referred to as the 'centrally held record'). During the review of traceability records, there was one instance where details of an allograft had not been recorded within the patient's theatre record. Although there was information in the record book, the establishment could not be certain the allograft had been used in the patient indicated.	**Minor**

GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The serious adverse events and reactions (SAEARs) reporting procedure states the laboratory should notify the DI of freezer temperature deviations. Communication from the laboratory during the inspection indicated this would not always happen.	**Minor**

D2 The reasons for disposal and the methods used are carefully documented.		
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.	Allograft disposal records were not consistent and did not always include the information set out in the documented procedure for allograft disposal.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 3 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

DI and CLH/LH suitability

Although the licensed activities are considered to be relatively low risk, the HTA is concerned about the recurrent nature of the shortfalls that were identified. As set out in Directions 001/2021, both the LH and DI are responsible for ensuring that human tissues are stored in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). Based on this inspection, the HTA believes there is an emerging pattern of a failure to meet the statutory obligations. The HTA intends to monitor the actions taken to address the shortfalls identified during this inspection in order to reach a decision on whether further action is needed in relation to this matter.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1d	The DI is advised to review all procedures and policies and update as required to ensure correct document labelling and cross referencing of related documents.
2.	GQ3e, GQ3f, GQ3g	If staff are not present for the training day, the DI is advised to carry out additional sessions so that training does not become overdue.
3.	GQ4b	The DI is advised to review how information is documented in the record book and ensure it is consistent and in line with the documented procedure.
4.	D1a	The documented procedure describing disposal of allografts makes reference to the Trust disposal of clinical waste policy. This policy was requested for review during the inspection but was not provided. The DI is advised to ensure related documents are available when required.

Background

The establishment is licensed for the storage of bone (femoral heads) and tendons, and for the procurement of cartilage as a starting material for an Advanced Therapy Medicinal Product (ATMP); the latter activity is not currently being undertaken.

The establishment has been licensed by the HTA since December 2010. This was the establishment's sixth inspection and consisted of an on-site inspection and Virtual Regulatory Assessment (VRA); the most recent previous inspection took place in June 2019. The licensing arrangements with respect to the storage of the allograft within the Pathology department which were highlighted during the previous inspection, were discussed. The HTA will give further consideration to this matter separately to the inspection findings reported below.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 2. The following areas were covered during the inspection:

Review of governance documentation
The inspection included a review of policies and procedural documentation relevant to the establishment's licensable activities including procedures describing receipt, storage and release of allografts. The review of quality management system documents included incident reporting procedures and audits.

Audit of records and other documentation
Seven records (six femoral heads and one tendon) relating to allograft receipt, storage, release and disposal were reviewed in conjunction with establishment staff. There was one instance where details of an allograft (a femoral head) had not been recorded within the patient's theatre record [see shortfall against standard GQ6b]. In addition, there was one incident in which an allograft was used approximately one month after the expiry date [see shortfall against standards PFE3c and PFE3d].

Equipment maintenance records, temperature records for the freezer and staff training records were also reviewed.

The internal audit of allograft receipt to release or disposal was reviewed.

Meetings with establishment staff
The inspection included discussions with the DI and the Trauma and Orthopaedics Theatre coordinator.

Report sent to DI for factual accuracy: 01 December 2021

Report returned from DI: 01 December 2021

Final Report issued: 06 January 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 20 January 2023

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.

m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.

h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.

m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.

f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.

PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
d) Records are kept of transportation and delivery.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.

c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.

b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections and VRAs carried out from 1 November 2010 are published on the HTA's website.

Appendix 3: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007, or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next on-site inspection or VRA.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the

issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.