Site visit inspection report on compliance with HTA licensing standards
Inspection date: **09 October 2019**

Royal Stoke University Hospital

HTA licensing number 12417

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

and

Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment

'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.

Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

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

Tissue types authorised for licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

'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, Tendon & Ligament;				**Authorised**			

Tendons							
Musculoskeletal, Cartilage; Cartilage (ATMP)	**Authorised***						
Ocular, Cornea; Cornea				**Authorised***			
Ocular, Sclera; Sclera				**Authorised***			

Licensed activities – Human Tissue Act 2004

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

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

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Royal Stoke University Hospital	**Licensed***

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Royal Stoke University Hospital (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found in relation to standards for Governance and Quality, and Premises, Facilities and Equipment. These related to the content of the documented procedures for licensable activities, procedures to be followed in the event of termination of activities, the establishment's oversight of temperature monitoring systems and the maintenance and cleaning of equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection

Compliance with HTA standards

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	The documented procedure (SOP 10) for the transfer of tissue products to the contingency freezer does not reflect current practice with regards to maintaining the temperature of the cool box during transport. Furthermore, the procedure sets out the temperature at which samples should be transferred to the contingency freezer; the current requirements are not aligned with the tissue supplier's storage recommendations.	**Minor**
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.	There are no procedures in place to ensure that in the event of termination of activities, stored tissues are transferred to another licensed establishment.	**Minor**

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.	Currently, the establishment uses two systems to monitor and record freezer temperatures. Information from the freezers' in-built temperature probes is used to inform whether tissue products can be released for end use. However, there was no evidence to demonstrate that these probes have been calibrated according to manufacturer's instructions.	**Minor**
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.	The establishment's freezers are maintained and cleaned by the estates department on an annual basis. However, there is no documented record of the maintenance and cleaning that is carried out.	**Minor**
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.		

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 2 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.

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

Number	Standard	Advice
1.	GQ1b	On receipt of tissue products, the integrity of the packaging and level of dry ice in the transport container is assessed. The DI is advised to record that these checks have been carried out. This record will provide assurance that the required temperature conditions have been maintained during transport and help to support any investigations in the future, if required.
2.	GQ2b	The DI is advised to consider including the 'Bone Freezer In Book' in the internal audit programme. This will help to identify and resolve any discrepancies between the receipt paperwork and the details entered into the book, the electronic tissue register and the allograft checklist.
3.	GQ2c	The current independent audit programme does not capture all of the work that was carried out. For example, a traceability audit of tissues was carried out, but this was not documented. The DI is advised to ensure that audit records reflect the full scope of the activities undertaken. This will help to provide assurance that compliance has been assessed against all applicable standards.
4.	GQ3f	The training programme and the quality manual currently only reference the Human Tissue Act 2004 (HT Act). The DI is advised to update these references to reflect the appropriate regulations where necessary. Establishments working in the human application sector are licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The DI is also advised to update the references made to the Codes of Practice in the quality manual, which were superseded in April 2017 and to consider whether the new Codes of Practice are relevant to the licensable activities.
5.	GQ4b	The DI is advised to regularly audit the temperature records for the completeness of data. The DI is also advised to consider annotating any temperature excursions and the reasons for the absence of data. This would enable the establishment to maintain a record of what happened at the time, identify trends to facilitate internal audit activities and help to improve storage practices.
6.	GQ4h	The DI is advised to review current arrangements for ensuring that the continuous temperature monitoring records are kept for 10 years after the use, expiry date or disposal of tissues and/or cells. The DI is advised to consider taking a copy of the temperature monitoring records and storing this locally to meet this

		regulatory requirement. A regular review process of the data may also help to provide better oversight of the freezer temperatures, and therefore assure the DI of the ongoing quality and safety of the stored tissues.
7.	GQ4m	Whilst the establishment falls under the Trust policy for record retention, the DI is advised to incorporate the procedures to be followed in the event of termination of activities within the quality manual. This will help ensure that records of raw data and traceability are maintained for 10 or 30 years as required after the use, expiry or disposal of the tissue products.
8.	GQ8a	The DI is advised to update current risk assessments to accurately reflect the maximum permitted time from the tissue product being dispatched to it being placed into the establishment's freezers. The DI is also advised to update the maximum temperature limit beyond which the tissue product would no longer be viable, and to complete the risk scores, some of which are currently absent.
9.	GQ8a, PFE5c	The DI is advised to regularly review the alarm status records on the wireless temperature monitoring system and to challenge the 24 hour alarm system. These checks will help to ensure that the alarms are working and staff are adequately alerted during any temperature excursions. The DI is also advised to include these checks as mitigating steps within the establishment's risk assessments so that the ongoing suitability of the alarms can be assessed.
10.	PFE3c	The DI is advised to record the movement and storage of tissue products from one freezer to another during routine maintenance. This will enable the freezer temperature records to be aligned with the location of the stored tissue products.
11.	PFE5c	The DI is advised to check that the alarm set points and alarm delay times for the wireless monitoring system are appropriate for the tissue products stored in the freezers and to document these parameters in the establishment's procedures. This will help to ensure that staff are able to respond to temperature excursions prior to the quality and safety of the tissues being compromised.

Background

The Royal Stoke University Hospital has been licensed by the HTA since October 2009. This was the sixth site visit inspection of the establishment; the most recent previous inspection took place in October 2017. The establishment maintains a stock of tissue products, including femoral heads, tendons and strut grafts, which are supplied by another HTA-licensed establishment. The establishment is also licensed to procure cartilage for use in the development of an Advanced Therapy Medicinal Product (ATMP), but this activity is not currently being carried out. Corneas and sclera are purchased for end use in the Ophthalmology department, but these are not currently stored for more than 48 hours. The establishment is also licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose under the HT Act. However, the establishment does not currently store any relevant material under the HT Act.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

During the inspection, compliance with 70 of the 121 standards under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) was assessed. The remaining 51 standards were not applicable. The establishment does not currently store relevant material for a scheduled purpose, therefore compliance with the standards under the HT Act were not assessed.

Review of governance documentation

The inspection included a review of documentation relevant to the establishment's licensable activities. This included policies and procedural documents, risk assessments, internal and independent audits, staff training records, temperature monitoring records, reported incidents and adverse events and governance meeting minutes.

Visual inspection

The visual inspection included a visit to the two theatres where the primary and contingency freezers used for storing tissue products were located. The Ophthalmology department was not inspected as they are not currently storing tissue for more than 48 hours.

Audit of records

A traceability audit was carried out of three tissue products randomly selected from the freezer. These were checked against the 'Bone Freezer In Book' and the electronic tissue register. Two minor discrepancies were found relating to the entry of an incorrect 'received' date, and the recorded expiry date of a product. Whilst these discrepancies were not sufficient to amount to a shortfall, advice was given to the establishment (see *Advice item 2*). Records from two patients who had tissue products implanted were reviewed and the disposal records for two tissue products were also reviewed. No discrepancies were identified.

Meetings with establishment staff

Round table discussions were held with the Consultant in Trauma and Orthopaedics, who is also the DI, the Senior Operating Department Practitioner/HTA lead, who is also a Person Designated (PD), the Matron, the Ophthalmology Staff Nurse and the Quality Assurance Manager.

Report sent to DI for factual accuracy: 06 November 2019

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 14 November 2019

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: 12 March 2020

Appendix 1: 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 2: 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 carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: 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 HT Act, 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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions,

   Or

   A number of 'major' shortfalls, none of which are 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 breach in the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures 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.

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 inspection.

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 the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: 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. The establishment does not store relevant material for a scheduled purpose therefore compliance with the standards under the HT Act was not assessed.

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

Governance and Quality
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.
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.
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 002/2018.
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 002/2018 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.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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.
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.

Premises, Facilities and Equipment
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.
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
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.