Site visit inspection report on compliance with HTA licensing standards
Inspection date: **17-19 September 2019**

Glenfield Hospital

HTA licensing number 11011

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*' = Establishment is licensed to carry out this activity but is not currently carrying it out.
'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

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

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub **Glenfield Hospital**	E*		TPA	E	E/TPA		
Satellite **Airedale General Hospital**				E			
Satellite **Bradford Royal Infirmary**				E			

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Satellite **Broomfield Hospital**				E			
Satellite **Calderdale Royal Hospital**				E			
Satellite **Spire Leicester Hospital**	E			E			
Satellite **Leicester General Hospital**	E			E			
Satellite **Lincoln County Hospital**				E			
Satellite **Norfolk and Norwich University Hospital**				E	E		
Satellite **Nuffield Orthopaedic Centre**				E			
Satellite **Pilgrim Hospital**				E			

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Satellite **Barlborough NHS Treatment Centre**	E			E			

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone	Authorised		Authorised TPA	Authorised	Authorised		
Musculoskeletal, Tendon & Ligament; Tendons, Menisci				Authorised	Authorised		
Cardiovascular, Valves; Heart Valves				Authorised			
Cardiovascular, Vessels; Conduits,				Authorised			

Licensed activities – Human Tissue Act 2004

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Hub site **Glenfield 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 Glenfield Hospital (the establishment) had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and Quality and Premises, Facilities and Equipment. These related to the content of the establishment's procedures, recording materials and consumables coming into contact with procured tissue, and temperature monitoring of critical reagents.

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.	During the inspection a number of examples were identified where the establishment's procedures did not reflect current practice. For example: • the procedure for the release of tissue from quarantine requires the operator to check the time from explant of the bone to the time that it is placed into quarantine storage, but the procedure does not specify what this timeframe is permitted to be; • procedures related to the implant of femoral heads do not provide users with instructions regarding the length of time that bone is permitted to be temporarily removed from freezer storage, and returned to the freezer if unused;	**Minor**

Standard	Inspection findings	Level of shortfall
	• procedures in use at procurement sites do not include instructions to the site relating to the taking and storage of blood samples for mandatory serological testing; and, • procedures for packing and transportation of tissue do not provide instructions to operators for the conditioning of cold packs prior to their use in the transport container.	
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	The establishment's procedures do not include instructions relating to the receipt of purchased orthopaedic tissues, or set out the checks to be undertaken upon receipt of purchased tissue.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
j) Records are kept of products and material coming into contact with the tissues and / or cells.	The establishment's procurement records do not capture the lot identification information for all materials, such as saline and sterile swabs, which come in to contact with bone during procurement.	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	Microbiological testing broths used during the procurement of bone and which are stored at a satellite site have a manufacturer's recommended storage temperature range of 2-25°C. The storage environment is not continuously monitored to enable establishment staff to identify if these stored broths have been subjected to any excursions from the manufacturer's specified storage temperature range. Broths stored at the hub site are stored in a room that is subject to continuous temperature monitoring. However, the relevant temperature probe is not routinely calibrated to help assure the DI that it remains accurate.	**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 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.

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

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

Number	Standard	Advice
1.	C2a	The information leaflet and consent form used in discussions with potential bone donors provide assurance to donors that they may halt the consent process at any time with no obligation to continue. The DI is advised to update these documents to clarify that donors can withdraw their consent to the donation, storage and use of their bone at any time, provided that the tissue has not already been used.
2.	GQ2b	The establishment's audit template used when auditing consent records sets out in detail the checks to be undertaken, and includes fields for the auditor to document which records were reviewed. The DI is advised to expand the use of this audit template to include audits undertaken at satellite sites, so that an equivalent level of evidence regarding records that are reviewed is captured.
3.	GQ4h	The establishment has an agreement with a third party undertaking temperature monitoring, and storage of the resulting data, on behalf of the establishment. The agreement with the third party currently states that the temperature monitoring data will be stored for up to 30 years. The DI is advised to amend this agreement during its forthcoming review so that it explicitly states that monitoring data will be stored for a minimum period that is aligned with the regulatory requirement.
4.	GQ7c	In the absence of the DI, responsibility for the reporting of serious adverse events and reactions (SAEARs) is delegated to the Deputy Medical Director. The DI is advised to add the Deputy Medical Director to the

		licence as a Person Designated (PD) so that they have access to the SAEARs reporting portal should it be needed.
5.	GQ8a	The establishment has commissioned a community nurse to collect blood samples for mandatory serology retesting 180 days after the donation of bone. The DI has risk-assessed this activity, and is advised to expand this assessment to include potential risks and relevant mitigating measures with regards to the appropriate storage of the testing samples between their collection and delivery to the testing laboratory.
6.	PFE4h	The establishment undertook a validation exercise of the boxes used to transport tissue when they were first purchased. The DI is advised to consider introducing a schedule for revalidating the boxes to help assure themselves that the boxes continue to perform as the establishment expects.

Background

Glenfield Hospital has been licensed by the HTA since October 2006. This was the seventh site visit inspection of the establishment; the most recent previous inspection took place in September 2017.

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

There are 121 standards in the Human Application sector of which 111 were assessed. Standards C1b, C2b, GQ1f, PFE1d PFE2b were not applicable. Standards C2c, GQ2d, GQ5e, GQ5f, and PFE4j were not assessed.

The establishment is also licensed for the storage of relevant material for use for a scheduled purpose under the Human Tissue Act 2004. The establishment does not currently store relevant material under the Human Tissue Act 2004 licence. Therefore, the applicable HTA

standards were not reviewed during this inspection.

Review of governance documentation
The inspection included a review of documentation relevant to the establishment's licensable activities. This included the quality manual, standard operating procedures, reference documents, controlled forms, records of servicing and calibration, temperature monitoring records, agreements with third parties, meeting minutes, reported incidents and adverse events, audits, risk assessments, and staff training records.

Visual inspection
The inspection team reviewed the equipment and systems relating to licensable activities at two satellite sites; Lincoln County Hospital and Spire Hospital, Leicester. At the hub site, the inspection included a visit to the area where femoral head stocks are stored in dedicated quarantine and release freezers and an inspection of the freezer in theatres used to store heart valves, vessels, tendons and menisci.

Third party establishments undertaking microbiological and serological testing on behalf of the establishment were not visited during this inspection.

Audit of records
Donor selection, consent, procurement, serological and microbiological testing, storage and release records for four femoral heads were audited during the inspection. A recording of a donor selection and consent seeking conversation that took place over the telephone was also reviewed. Stock lists at Lincoln County Hospital were compared with the satellite site's actual freezer contents and the establishment's electronic stock databases at the hub. Stock held in the hub storage freezer in theatres was compared with the stock database and paper records. No discrepancies were identified.

During the visit to the satellite site at Lincoln County Hospital, a routine check of the temperature monitoring alarm system was undertaken. The alarm operated as expected with the third party undertaking temperature monitoring alerting establishment staff to the temperature excursion. The temperature excursion was captured in the establishment's temperature monitoring records, which were reviewed at the hub site following the visit to the satellite.

Meetings with establishment staff

The inspection included meetings with the Medical Director (who is the DI), the Head of Service/Quality Manager, the Assistant Head of Service and the Deputy Service Manager. The inspection team also met with staff at the satellite sites who were involved in donor selection, consent, procurement, sample handling, and storage (quarantine and end use) activities.

Report sent to DI for factual accuracy: 15 October 2019

Report returned from DI: 28 October 2019

Final report issued: 31 January 2020

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: 17 March 2021

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 Human Tissue Act 2004 (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 both the draft and 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.