Inspection report on compliance with HTA licensing standards
Inspection date: **30 March 2022**

School of Medicine (Anatomy Facility), Keele University

HTA licensing number 12190

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
School of Medicine (Anatomy Facility), Keele University	Licensed	Licensed	Licensed	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. School of Medicine (Anatomy Facility), Keele University (the 'establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C2(a)	Current training in the seeking of consent involves the reading of specific standard operating procedures (SOPs) and the shadowing of experienced staff. The DI is advised to consider formalising these requirements in a training, and refresher training, programme. This will help to ensure that existing, and new, staff can demonstrate competency in seeking consent.
2.	GQ2(a)	Regular horizontal and vertical audits are carried out by establishment governance staff. The DI is advised to consider including procedural audits in this schedule to ensure that all practices fall under the establishment's ongoing monitoring.
3.	GQ2(b)	Audit findings and actions taken are recorded inconsistently. The DI is advised to formalise the processes of recording audit findings, documenting discussions about audits, recording personnel responsible for follow-up actions and documenting the timeframes for completing these.
4.	PFE1(c)	There are documented cleaning and decontamination SOPs but cleaning and decontamination is not recorded consistently. The DI is advised to consider setting up a formal schedule to record cleaning and decontamination of both facility and storage units.
5.	PFE2(c)	The establishment has a continuous temperature monitoring system for its storage units. The DI is advised to consider regular challenging of the temperature alarm callout system and the audible

		temperature alarms to ensure that they function as expected. In addition, the DI is advised to consider initiating a programme by which, at suitable intervals, the temperature plots from the freezer are reviewed. This may help to identify a potential failure of this equipment before it occurs.
6.	PFE3(a)	Storage units are subject to regular maintenance by external contractors. The DI is advised to consider keeping a record of contractor service reports to ensure storage unit performance is regularly monitored.
7.	PFE3(a)	The DI is advised to ensure that all storage unit maintenance and probe calibration contracts are kept up to date. This will help to provide assurances that equipment remains suitable for use.

Background

School of Medicine (Anatomy Facility), Keele University accepts approximately 50 body donations each year from individuals registered predominantly in the regions of North Wales, West Midlands, and parts of North West England and East Midlands. The formalin-embalmed or soft fix-embalmed bodies are stored, along with prosections, in temperature-monitored 4ºC refrigerated units before being used for teaching anatomy to undergraduate and postgraduate medical students, nursing, midwifery, physiotherapy and osteopathy students as well as biomedical science students. The establishment also receives consented fresh-frozen whole-body donations from donors as well as from a separate HTA-licensed establishment under agreement. Fresh-frozen body parts are also imported from the USA. Bodies and body parts are stored in a temperature-monitored -20ºC freezer unit and are used for education and training of healthcare professionals.

The establishment also has collections of skeletal specimens, formalin-fixed adult and foetal tissue, formalin-fixed paraffin wax-embedded blocks and sections, plastinated specimens and frozen placentas (from living donors) for education and training purposes.

The establishment occasionally loans anatomical and former anatomical specimens to HTA-licensed establishments under the terms of a service level agreement.

The establishment has been licensed by the HTA since May 2007. This was the second inspection of the establishment; the last one took place in September 2013.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in 2018, the current Corporate Licence Holder contact (CLHc) was registered with the HTA in 2022, 15 Persons Designated (PDs) have been added to the licence (and three removed).

Description of inspection activities undertaken

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

Standards assessed against during inspection

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the licensed activities, cleaning records for the storage areas and dissection room, temperature monitoring records for the storage units, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, minutes of meetings, the management of complaints, staff training records, and risk assessments.

Three of the establishment's internal audits, one external audit and three reported adverse events were reviewed.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

No formal audit of records was carried out by the HTA.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, CLHc and three PDs. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 28 April 2022

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

Final report issued: 02 June 2022

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

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) or associated Directions.

1. **Critical shortfall:**

   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 combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   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 that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

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, but which indicates a departure from expected standards.

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

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