Inspection report on compliance with HTA licensing standards
Inspection dates: **10 July 2023 (remote) and 11 July 2023 (site visit)**

University of Northumbria at Newcastle
HTA licensing number 12482

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
University of Northumbria at Newcastle	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.

Although the HTA found that the University of Northumbria in Newcastle ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems and Traceability standards.

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

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ4 There is a systematic and planned approach to the management of records		
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.	There was no records management policy in place that sets out the retention periods for all records pertaining to specimens. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored.		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The risk assessments were found to be limited in scope and did not take into consideration all risks relevant to activities taking place. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
b) A register of donated material, and the associated products where relevant, is maintained.	At the time of the inspection, it was difficult to identify key information relating to some specimens during the audit trail as there was no central register where all the information is kept. Although paper records did exist, it was difficult to establish the information required during the audit trail in an efficient way. Previous audits are relied on to confirm which specimens are held meaning there is a risk that records may not be up-to-date. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner.		
a) Disposal is carried out in accordance with the HTA's Codes of Practice.	The 'Anatomy Teaching Facility Operations Manual' does not state that the reason and method of disposal should be documented. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**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.

Advice

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

Number	Standard	Advice
1.	GQ1(d)	Although there are monthly operations meetings to discuss activities taking place in the Anatomy Teaching Facility, the meeting discussions are not minuted. Actions arising are documented and circulated via email after a meeting. To strengthen this further, the DI should consider keeping a formal record of the meeting discussions; for example, so that staff can access and review these in case they are unable to attend.
2.	GQ3(b)	The DI should consider implementing a process to record competency of new staff undertaking key tasks as part of their training. This may help supervising staff to monitor the progress of new staff

		throughout their induction.
4.	GQ5(a)	The DI should consider creating an incident log for all incidents that occur in the Anatomy Teaching Facility. Although incidents are reported to the DI as they arise, only ones that will be investigated are documented. Maintaining a record of all incidents may enable the DI to identify trends and therefore suitable preventive and corrective actions.
5.	T2(a)	The establishment stores whole bodies imported from outside of the UK. The DI is advised to document the process for their return or disposal, taking into consideration any requirements set out by the supplying organisation.

Background

The establishment provides postgraduate courses to students studying anatomy and stores imported plastinated specimens, for students to view during teaching. The establishment stores a static collection of catalogued plastinated specimens, with the most recent parts imported in 2018.

This was the third inspection of the establishment; the most recent previous inspection took place in April 2014. 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

44 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards T1(d),(f) and (g) were not applicable, as the establishment maintains a static collection of imported plastinated material and does not receive or loan parts out to other establishments.

Review of governance documentation

A review of policies and procedural documents relating to licensed activities, cleaning records for the storage areas and dissection room, contracts for servicing of equipment and records of servicing, audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents, and staff training records was carried out.

Visual inspection

A visual inspection of the Anatomy Teaching Facility, which contains a storage room where all specimens are stored, was carried out. The review also included security of the premises and access to students.

Audit of records

Storage location one

An audit of two plastinated bodies was carried out from storage locations to records. One of the bodies did not have the expected bar code label although another label was present to provide correct identification. This was noted as a minor discrepancy. An audit of the viscera of one of the bodies was also carried out from record to storage location. No discrepancies were identified.

A further audit of a specimen was carried out from storage to location of records. No discrepancies were identified.

VH Cabinet

An audit was carried out from records to storage location of a plastinated body part. No discrepancies were identified.

Display cabinet

An audit was carried out from records to storage location of a plastinated specimen. No discrepancies were identified.

Meetings with establishment staff

Meetings were held with staff carrying out processes under the licence, including the DI and Persons Desigated (PDs).

Report sent to DI for factual accuracy: 26 July 2023

Report returned from DI: 5 September 2023

Final report issued: 5 September 2023

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.