Inspection report on compliance with HTA licensing standards
Inspection date: **30 April 2024 and 1 May 2024**

University of Nottingham
HTA licensing number 12085

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
Hub site- University of Nottingham	Licensed	Licensed	Licensed	Licensed
Satellite site- Royal Derby Hospital	Licensed	Licensed	Licensed	Licensed
Satellite site- Lincoln Medical School	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.

University of Nottingham ('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.	GQ1(a)	'HTA' is referenced within the establishment's Code of Conduct; however, it is abbreviated from the start of the document. To avoid confusion and clarify the abbreviation, the DI is advised to reference the 'Human Tissue Authority' when the name is first used in the document.
2.	GQ1(a)	The SOP for the 'Receipt of Cadavers' details that identification checks take place on arrival however it does not detail specifically what the body identification is checked against. The DI is advised to include this level of detail
3.	GQ1(b)	There is a document register with the details of all Anatomy documents including staff distribution lists. There are some members of staff for whom there are outstanding document acknowledgments. The DI is advised to review the lists and chase up any outstanding acknowledgments if necessary to ensure

		that all staff working under the licence have read and understood the most recent versions of the SOPs.
4.	GQ2(a)	To provide greater assurance on security, the DI is advised to expand the range of internal audits to include audits of security measures and facility access records at both satellites.
5.	GQ5(a)	The establishment has a detailed SOP outlining the process for incident reporting. To improve staff awareness, the DI is advised to provide examples of what types of incidents are to be reported that relate to licensed activities, such as specimen loss, incorrect documentation, use of relevant material without appropriate consent, loss of dignity of the deceased and loss of traceability (this is not an exhaustive list).
6.	PFE1(b)	The DI may wish to consider the use of security cameras to supplement existing security arrangements and to monitor adherence with key activities.

Background

University of Nottingham has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in July 2015.

Since the previous inspection, there have been significant changes to the licence arrangements and the activities carried out under the licence. There have been changes to the DI in August 2020 and November 2023. There has also been an addition of a satellite site at Lincoln Medical School in October 2019 and a revocation of the satellite licence for the School of Veterinary Medicine and Sciences in March 2024.

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 Regulation Manager reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures (SOPs), policies, anatomy suite Code of Conduct, risk assessments, cleaning records for the storage areas, laboratories and anatomy suites, traceability databases for whole cadavers, prosections, potted specimens and bones and documentation relating to the bequeathal process.

Visual inspection

The Regulation Manager undertook a site visit inspection of the hub and both satellite sites. At the University of Nottingham this included the Bequeathal office, preparation room, storage rooms, embalming area and anatomy suite. At Royal Derby Hospital this included the anatomy suite and storage area. At Lincoln Medical School this included the anatomy laboratory and storage area.

Audit of records

At the hub site, the Regulation Manager undertook traceability audits for whole cadavers in the department. This included one body that was stored in the freezer, one being used for teaching, one being processed and one fully dissected for teaching. Traceability details were crosschecked between the identification bands on the body and information on the electronic and paper records through to consent documentation. Four potted specimens from the museum collection were also audited. Traceability details were crosschecked between the identification details on the specimen and information on the electronic database. No discrepancies were identified.

At the satellite site at Royal Derby Hospital, the Regulation Manager undertook traceability audits for six prosections in storage. Traceability details were crosschecked between the identification labels on the specimen, information on the electronic and paper records through to consent documentation. No discrepancies were identified.

At the satellite site at Lincoln Medical School, the Regulation Manager undertook traceability audits for four prosections in storage. Traceability details were crosschecked between the identification labels on the specimen, information on the electronic and paper records through to consent documentation. No discrepancies were identified.

Meetings with establishment staff

The Regulation Manager met with staff carrying out activities under the licence, including the Anatomy Teaching Prosecting Manager, an Anatomy Teaching Prosector, the Anatomy Bequest Coordinator, and an Associate Professor who is the DI.

Report sent to DI for factual accuracy: 8 May 2024

Report returned from DI: 14 May 2024

Final report issued: 17 May 2024

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.