Inspection report on compliance with HTA licensing standards
Assessment dates: **8 March 2023 (site visit)**

University of Cambridge

HTA licensing number 12146

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 Cambridge, Downing site (Hub)	Licensed	Licensed	Licensed	Licensed

Ipswich Hospital (Satellite)	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.

The HTA found that the University of Cambridge (the 'establishment') had met all of the HTA's standards.

Advice

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

Number	Standard	Advice
1.	C1(a)	The DI may wish to consider updating the standard operating procedure (SOP) that outlines the process for seeking consent to include an example of a correctly completed consent form. This should support new staff involved in the bequeathal process to ensure that only conforming consent forms are accepted.
2.	C1(d)	The DI is advised to review and revise the bequest information sheet, as two different issue dates are included in the footer.
3.	GQ1(a)	The Quality Manual (QM) also contains all standard operating procedures, policies and risk assessments. The DI is advised to remove the SOPs, policies and risk assessments from the scope of the QM so that these can be managed as separate documents. This will reduce the frequency of amendments made to the QM whenever

		a change is required to one or more of the component documents.
4.	GQ1(b)	At the time of the inspection the establishment was using an excel spreadsheet as a quality management system to manage all SOPs and governance documents. The DI should consider adding the review dates for each SOP to enable a systematic approach to document review.
5.	GQ2(a)	Staff at the establishment undertake regular audits, covering consent and traceability of stored cadavers and parts. To widen the scope of activities covering by auditing, the DI should also consider audits tracing the receipt of cadavers through to disposal and include observational audits of staff undertaking activities against SOPs.
6.	GQ3(b)	The DI and the Human Anatomy Centre Manager had recently reviewed the approach to assessing staff competency as the general induction of staff had previously been managed separately by Human Resources. The Human Anatomy Centre Manager shared an example of how the probation review now includes confirmation of staff competency and the requirement to meet particular criteria if working under the licence. To improve this further, the DI should review the approach to documenting staff competency and add key dates for when a staff member has been observed successfully performing a particular process.
7.	GQ5(a)	The Adverse Event Policy includes a definition of a serious adverse event (SAE), which is applicable to the Human Application sector definition under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). This is not relevant to Anatomy sector establishments.
8.	PFE1(b)	Although the door to the cadaveric and the pathological wet specimens storage areas is typically locked during teaching and is inaccessible to students, the DI may wish to consider keeping it locked as part of normal practices to further improve security.

Background

The establishment (hub and satellite) is licensed for the full suite of anatomy sector activities, with students attending the dissection room as part of medical courses each week. The establishment has a Human Anatomy Centre Manager, who oversees the body donation programme. It was noted that a turnover of staff in the Bequeathal Secretary role had placed pressures on the body donation programme.

The establishment carries out cadaveric dissection and also supports a programme of research for students undertaking intercalated degrees. The establishment does not carry out plastination of bodies and there is no surgical skills training using fresh frozen body parts.

All areas where bodies are received, embalmed, stored and dissected are secured with swipe access control. All students and visitors are expected to sign in and follow the establishment's guidance on conduct within the dissection room. This was the second inspection of the establishment; the last one took place in September 2013. The establishment loans temporal bones to the satellite site (Ipswich) under the governance of an agreement for a short period of time. No other activity takes place at the satellite site and the DI carries out an audit of the premises at the satellite site once a year. A discussion took place around the requirement for satellite site licensing given the limited scope of activity; however, it is likely that the level of activity may increase in the future.

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 assessment:

Standards assessed against during the inspection

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

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to licensed activities, audits, risk assessments for health and safety, adverse incidents, staff training records, visitor management policies and visitor codes of conduct. Audits were also reviewed.

Visual inspection of the hub site

A visual inspection was conducted during the visit to the hub site. No storage was taking place at the satellite site at the time of the inspection. The visual inspection included the embalming area, dissection room, cadaveric storage room, storage of parts room and wet specimen cabinets located in the dissection room.

Audit of records

Four forward audits were conducted for bodies in storage (location to records), which included three bodies stored prior to dissection and one in the dissection room. The consent forms for each were also checked for each donor along with consent for retention of parts. No discrepancies were identified.

A forward audit was carried out (location to records) of a stored anatomical specimen that was also used for research. The associated consent form was also checked. No discrepancies were identified.

A forward audit of a retained pelvis was carried out (location to records). The associated consent form was also checked for retention of parts. No discrepancies were identified.

Meetings with establishment staff

The inspection included discussions with the DI, the Human Anatomy Centre Manager and the temporary bequeathal secretary.

Report sent to DI for factual accuracy: 29 March 2023

Report returned from DI: 31 March 2023 (with comments)

Final report issued: 18 April 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 site visit 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 site visit.

   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.