Inspection report on compliance with HTA licensing standards
Inspection dates: **27 & 28 August 2024 (remote) and 16 September 2024 (site visit)**

University of Surrey
HTA licensing number 12547

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 Surrey	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 Surrey ('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)	Consent procedures are documented within the ‘Acceptance of Cadaveric specimens’ SOP and ‘Consent for Using Cadaveric Specimens’ SOP. Both documents clearly outline the consent requirements associated with anatomical examination; however, they do not detail the requirements relating to the signed Medical Certificate of Cause of Death (MCCD) and the death registration of the donor. Staff at the establishment do not consent donors directly and there is a Service Level Agreement in place with a third party to ensure that the donation is in line with legislation; however, for completeness and to maintain awareness of accepting staff, the DI is advised to also reference these requirements within the SOPs.
2.	GQ6(a)	There is a small lift and specific trolley to transport cadavers up to the first floor anatomy suite. The DI is advised to include the use of both the lift and trolley within the establishment’s risk assessments as failure of either would impact the expected process of receipt. Although not documented within risk assessments, the establishment was found to have mitigating actions and a contingency process in place.

3.	PFE1(a)	The establishment is currently awaiting a formaldehyde monitor. While also adhering to Health and Safety requirements, the DI is advised to have this monitoring system in place prior to the storage and use of any embalmed specimens or bodies.
4.	PFE1(b)	A motion sensor for the intruder alarm within the dissection room is close to a racking unit and privacy screen. The DI is advised to check that the sensor is not obscured and can operate as intended.
5.	PFE3(a)	The new fridge and freezer facilities are under an annual servicing contract; however, there have been difficulties getting similar arrangements for the two older chest freezers. If an external contract is not available, the DI is advised to maintain the units 'in-house' and formalise these checks so that the units remain in good working order and fit for purpose.

Background

University of Surrey has been licensed by the HTA since June 2009. This was the second inspection of the establishment; the most recent previous inspection took place in June 2016.

Since the previous inspection, there have been significant changes to the licence arrangements and the activities carried out under the licence.

In May 2024, the following changes were requested and actioned:

1. New Corporate Licence Holder contact (CLHc) and Designated Individual (DI)
2. Establishment name changed from 'Minimal Access Therapy Training Unit' to 'University of Surrey'
3. Activities were added to licensing arrangements, namely carrying out of an anatomical examination, storage of an anatomical specimen and removal from the body of a deceased person.

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

41 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).
Some standards relating to consent were not applicable as the establishment does not seek consent directly from donors (C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)).

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, the anatomy suite Code of Conduct, quality manual, training requirements and risk assessments. During the site visit, the establishment's electronic sample traceability system and database were also assessed.

Visual inspection

The Regulation Manager undertook a site visit inspection of the premises which included the shared spaces used by the University of Surrey and the Minimal Access Therapy Training Unit. The anatomy suite comprised of a dissection room, preparation room and storage room.

Audit of records

The Regulation Manager undertook traceability audits for specimens in the department. This included five dissected bodies that were stored in the refrigerator having been used for a surgical skills training course. Traceability details were crosschecked between the

identification bands on the body parts and information on the electronic and paper records through to consent documentation. No discrepancies were identified.

Meetings with establishment staff

The Regulation Manager met (virtually or in person) with staff carrying out activities under the licence. This included the Clinical Assurance Manager, Head of Assurance, Anatomy lecturers, the Senior Laboratory Technician, the Manager of the Minimal Access Therapy Training Unit and the Head of Anatomy who is the establishment's DI.

Report sent to DI for factual accuracy: 4 October 2024

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

Final report issued: 23 October 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.