Inspection report on compliance with HTA licensing standards
Inspection date: **15 December 2022**

University of Lincoln

HTA licensing number 12678

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
University of Lincoln	Licensed	Not 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 University of Lincoln ('the establishment') was found to have met most of the HTA's standards; however, three minor shortfalls were identified against Governance and quality systems (GQ) standards relating to governance meetings, audits and risk assessments.

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 assessment.

Compliance with HTA standards

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment works are governed by documented policies and procedures as part of the overall governance process		
GQ1(d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	The Human Tissue Oversight Group is used to discuss matters relating to HTA-licensed activities but was found to have not met since February 2022.	**Minor**

Standard	Inspection findings	Shortfall
GQ2 There is a documented system of audit		
GQ2(a) There is a documented schedule of audits covering licensable activities	The DI has undertaken spot checks of samples in storage but these have not been documented and there is no formalised audit programme.	**Minor**

Standard	Inspection findings	Shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
GQ6(a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice	There are no documented risk assessments for practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	**Minor**

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 adopting an approach where consent-seeking staff check the completeness of consent forms at the time the forms are completed. This may help to ensure that any issues with the completion of the consent forms can be rectified earlier.
2.	C2(a)	The DI provides HTA consent training to all consent seeking staff before they work with human tissue and maintains a log of trained staff. The DI may wish to consider amending the list so it is clear who the active consent seekers are. This may help to plan for refresher training before it is due.

3.	GQ1(a)	There are standard operating procedures (SOPs) in place for staff who carry out licensed activities. At the time of the inspection, the level of activity under the licence was limited, with only one member of staff working with human tissue. As the activity increases, the DI is advised to review the existing documentation and consider whether it remains suitable to enable new staff to follow a procedure from beginning to end. For example, the DI should consider whether procedural documents are detailed enough to ensure uniformity between staff in the performance of a specific function.
4.	GQ3(d)	Although there have not been any new starters since the licence was granted, as activities increase, the DI should consider developing a competency framework for staff working with human tissue.
5.	GQ4(a)	The DI is advised to review the University's records management policy to ensure that consent forms are retained for an appropriate length of time and to reduce the risk that consent forms are destroyed whilst samples remain in storage.
6.	PFE2(c)	The DI should consider adding a sign to show the low and high temperature trigger points for the freezers. This may help to guide staff on taking appropriate action/s should temperatures be outside of the expected range.
7.	PFE3(d)	HT-QMS-HT05-W101 is a procedural document that contains the steps to be taken in the event of a freezer failure. For ease of reference, the DI may wish to consider keeping a physical copy of this document in the critical storage area.

Background

The establishment was issued with their licence in 2018. There was limited tissue storage taking place at the time of the inspection, with saliva and fat cells being the only tissue types stored under the governance of the HTA licence. This report describes the establishment's first HTA inspection.

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

Of the 47 HTA standards, 42 were assessed (standards published 3 April 2017). Standards T1(d) – (g) were not applicable because the establishment had not transported any tissue and PFE2(b) was also not applicable.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff competency records and records relating to traceability.

Visual inspection

A virtual tour of the storage area was undertaken as part of the virtual regulatory assessment.

Audit of records

There was no auditing of records during the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI, Senior Lecturer in Psychology and Research Governance Administrator.

Report sent to DI for factual accuracy: 9 January 2023

Report returned from DI: 20 January 2023 (with comments)

Final report issued: 25 January 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 22 November 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.