Inspection report on compliance with HTA licensing standards
Inspection date: **18 July 2023**

Edge Hill University

HTA licensing number 12632

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
Edge Hill University	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.

Although the HTA found that Edge Hill University ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems.

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

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment did not have standard operating procedures (SOPs) covering receipt of relevant material and use of the tissue tracking database.	**Minor**
c) There are change control mechanisms for the implementation of new operational procedures.	The establishment did not have change control mechanisms in place to take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.	**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.	C1(d)	The DI is advised to consider amending the Patient Information Sheet template to include wording covering the export of relevant material for use abroad or where research is known or is likely to involve the commercial sector to ensure transparency during the consent process.
2.	C2(b)	The establishment had comprehensive consent training in place for staff and students; however, the consent training records were not signed-off or dated as completed by the DI and/or training assessor in all instances. The DI is advised to ensure consistency in the way training records are maintained for completeness of auditable information.
3.	GQ1(a)	Overall, the establishment had a comprehensive suite of documented policies and procedures. To improve these further, the DI is advised to consider the following: • including updated waste disposal contractor details • including the updated name of the contact acting as relevant material complaint handler • collating the collection of relevant material SOPs, for example, blood and saliva within the QMS • stating the review period of risk assessments • providing a link to the University's transport and packaging SOP for samples to be transferred to other organisations • including more detail on the use of disinfectant to dispose of liquid relevant material • defining the grading of adverse events
4.	GQ1(d)	Governance meetings are held every four months to discuss HTA licensable activities. The DI is advised to consider producing a standing agenda with relevant headings to formalise the process and ensure all areas

		relating to the licence are identified and discussed during governance meetings.
5.	GQ2(b)	Researchers are required to self-audit samples and associated documentation throughout the year. The DI is advised to formally document this audit activity and record all audit findings and related corrective and preventative actions to evidence and demonstrate compliance with HTA standards.
6.	GQ2(b)	Audit findings included who was responsible for follow-up actions and the DI is advised to implement timeframes for audit follow-up actions to be completed and resolved in a timely manner. In addition the DI is advised to consider characterising follow-up actions with a unique identifier to aid traceability of auditable information.
7.	GQ2(b)	Non-compliances had been identified in audits undertaken by the establishment and corrective actions taken. The DI is advised to ensure that corrective actions conclude with documented confirmatory evidence that the remedial action has been completed before closure for completeness of auditable information.
8.	PFE2(c)	The establishment operates a real-time temperature monitoring system to monitor the relevant material storage areas. The DI is advised to manually test temperature alarms to ensure the monitoring and call out system are operating as expected in order to provide additional assurance that storage conditions can be maintained and acted upon when temperatures are out of range.
9.	PFE3(b)	Users are informed how to report an equipment problem within the QMS. The DI is advised to consider the placement of signage containing pertinent equipment maintenance contact information within the relevant material storage areas to expediate response action.

Background

The establishment stores relevant material for use for the scheduled purposes of ‘Research in connection with disorders, or the functioning of the human body’ and ‘Education or training relating to human health’.

Edge Hill University has been licensed by the HTA since 17 June 2015. This was the first inspection of the establishment.

Since the licence application assessment, a new Designated Individual has been appointed but there have been no significant changes to 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

46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard was not applicable as the establishment did not store bodies or body parts [standard PFE2(b)] under the research licence.

Review of governance documentation

The inspection comprised a review of documentation relevant to the establishment's licensed activities including; policies and procedural documents, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, staff training records, temperature monitoring for the relevant material storage units and audits.

Visual inspection

No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the relevant material storage areas.

Audit of records

The establishment was unable to provide access to the tissue tracking database on the day of inspection and a traceability exercise was not completed. However, a review of the establishment's internal audits and their associated findings provide assurance that relevant material samples are traceable.

Meetings with establishment staff

The inspection included virtual meeting with the following staff: the Designated Individual (DI), two Persons Designated (PD), and the Chair of the Human Tissue Management Sub-Committee. The meeting covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 31 July 2023

Report returned from DI: 11 August 2023

Final report issued: 14 August 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: 7 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.