Inspection report on compliance with HTA licensing standards
Inspection dates: **26 June 2023 (remote assessment) and 27 June 2023 (site visit)**

Hull York Medical School (HYMS)
HTA licensing number **12078**

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 **Hull York Medical School (HYMS)**	Licensed	Licensed	Licensed	Licensed
Satellite site **Daisy Tumour Bank**	Not licensed	Not licensed	Licensed	Not licensed
Satellite site **HYMS**	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.

Although the HTA found that Hull York Medical School ('the establishment') had met the majority of the HTA's standards, one minor shortfall was identified against Governance and quality systems, specifically the absence of a risk assessment relating to transport.

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

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored.		

a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice	Although there was a documented risk assessment of transport, this did not reflect the risks associated with the transport of bodies and prosections between hub and satellite sites. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**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(a)	To strengthen consent procedures, the DI should consider including examples of consent forms that have been completed correctly. This should help to further support new staff to follow the correct procedures and understand requirements.
2.	C1(a)	The consent procedure contains information for staff on the withdrawal of consent but the steps to take to withdraw a donor and their records are contained in the records management procedure. As the information about the process is held in two separate procedures, the DI should consider how best to link the two to ensure that staff are clear on how to follow the whole process.

3.	C1(d)	To improve the information provided to donors, the DI should consider adding further detail on the storage and use of donor material for research. Although the donor information sheet does state that material could be stored and used for research in connection with the functioning of the human body, there is scope to improve the quality of this information to ensure that consent obtained is informed.
4.	GQ3(a)	To support training and the maintenance of competence, the DI should consider developing a competency framework for new staff which documents when they are signed-off to carry out a particular task and deemed competent to complete a task independently, where appropriate.
5.	GQ4(a)	The DI should consider including a regular audits of electronic traceability records to minimise the risk of data entry errors that may occur through manual entry of information.
6.	PFE2(d)	Contingency plans are described in ‘SOP 16, Adverse Events’. To improve understanding and adherence to existing plans, the DI is advised to include more detail on procedural steps; for example, for moving bodies from the hub to the satellite site.

Background

Hull York Medical School provides courses to undergraduate medical students and those working for Masters degrees. This was the third inspection of the establishment; the most recent previous inspection took place in March 2015.

The establishment undertakes a range of activities, including anatomy dissection, surgical skills training and plastination of specimens. Bodies and prosections are stored at the hub site and transferred to the satellite for smaller courses, currently linked to Masters degrees. Specimens are transferred back to the hub site for disposal. The establishment also stores material for research.

Since the previous inspection, there have been no significant changes to the licence arrangements or 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

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017)

Review of governance documentation

Documents reviewed included: policies and procedural documents relating to licensed activities, cleaning records for the storage areas and dissection room, contracts for servicing of equipment and records of servicing, audits, meeting minutes, risk assessments, temperature logs for the storage units, reported incidents, and staff training records.

Visual inspection

The hub and satellite sites were visited as part of the inspection and different areas were reviewed from point of receipt, storage, dissection and disposal. At the time of the inspection all dissection activities were completed for the academic year.

The Daisy Tumour Bank was not visited as part of this inspection as it will be inspected after it becomes a satellite of another licence.
Audit of records

Hub site (Hull)

A 'forward' audit of a body from storage location to consent and traceability records was carried out. There were no discrepancies identified. A reverse audit of a body (with brain and skin tissue removed) from consent records and the traceability system to current location was carried out. There were no discrepancies identified. The brain was traced from Hull to York and its physical location was

checked as part of the audit trail along with the physical location of the skin tissue, which was being stored for use in research. There were no discrepancies identified.

Audits of two prosected parts, from storage locations to consent and traceability records, were carried out. There were no discrepancies identified.

Satellite site (York)

Audits of two prosected parts, from storage locations to consent and traceability records, were carried out. There were no discrepancies identified.

A ‘forward’ audit of a prosected part from storage location to consent and traceability records was carried out. The consent records were checked. A minor discrepancy was noted, where two labels were attached to the part but with different years. This was corrected immediately and a new label attached. No further discrepancies were noted.

‘Reverse’ audits of two prosected parts used for surgical skills training, from consent and traceability records, was carried out. There were no discrepancies.

Meetings with establishment staff

There were meetings with the DI and Corporate Licence Holder contact (CLHc) and key staff working under the licence, including the Mortuary Managers from both hub and satellite sites, Bequethal Manager, Technical Services Manager and the Human Tissue Compliance Manager.

Report sent to DI for factual accuracy: 18 July 2023

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

Final report issued: 11 August 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.