Inspection report on compliance with HTA licensing standards
Inspection dates: **16 January (remote) and 18 January (site visit) 2024**

Bangor University
HTA licensing number 12546

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
Bangor University (Hub)	Licensed	Licensed	Licensed	Licensed
Department **School of Healthcare Sciences, Archimedes Centre (Satellite)**	Not licensed	Not licensed	Not 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 the Bangor University (‘the establishment’) had met most of the HTA’s standards, eight minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment.

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
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.	Some documented procedures were not relevant to the activities undertaken at the time of the inspection and the ones that were did not contain enough detail to enable a member of staff to carry out the activity described. Furthermore, there were no standard operating procedures (SOPs) in place for the activities being undertaken by the establishment.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Although an inventory audit was performed prior to the inspection, this was not documented.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	The establishment does not have in place a documented process for how actions arising from an audit are documented and followed up, for example, there were some discrepancies and observations, identified during a recent audit, that required correction which had not been documented	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
a) Qualifications of staff and all training are recorded, records showing attendance at training.	The staff involved in the delivery of the courses are experienced but training was not recorded.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
b) There are documented induction training programmes for new staff.	There was no documented induction training programme available for new staff or those who may provide support on an ad-hoc basis.	**Minor**

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.	There are no documented risk assessments covering risks relating to licensable activities.	**Minor**

PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures.	There is no documented procedure for cleaning of areas where licensed activities take place.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	There are no documented contingency plans in the event that the material would need to be moved in an emergency.	**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.	GQ2(a)	The DI should consider extending the scope of audits to include audits covering processes and procedures. This will help to broaden the schedule of audits and provide the DI with wider assurance.
2.	T2(a)	In documenting disposal procedures, the DI is advised to include any relevant known disposal considerations for imported material.

Background

The establishment stores a collection of brains that have been purchased from commercial providers or supplied under agreement from other HTA-licensed establishments. They use the brains for undergraduate and postgraduate neuroanatomy teaching courses; the undergraduate course is run up to four times each year and the postgraduate course is run once each year.

The establishment's activities have changed since the last inspection, with a move to non-dissection activities. They are no longer storing body parts from another HTA-licensed establishment.

This was the third inspection of the establishment; the most recent previous inspection took place in 2014.

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

A review of policies and procedural documents relating to licensed activities, service records, meeting minutes, consent forms and traceability records were undertaken.

Visual inspection

A visual inspection of the laboratory where brains are stored was carried out. The review included security of the premises and access for students. A visit to the satellite site was not undertaken, as the establishment plans to transfer all specimens to the hub. The inspection teams were provided photographic evidence of the storage area at the satellite and its security.

Audit

A traceability audit from records to brains in storage was carried out for four specimens. The consent records for each brain were also reviewed. There were no discrepancies noted.

An additional audit of consent records was undertaken for four brains. All brains had appropriate consent in place for storage for a scheduled purpose.

A review of the records relating to the return of prosections to HTA-licensed premises in November and December 2023 was undertaken. The records indicated that the material had been transferred and received by the other establishment. No discrepancies were noted.

Meetings with establishment staff

Meetings were held with staff carrying out processes under the licence, including the DI, Corporate Licence Holder contact (CLHc) and Persons Designated (PDs).

Report sent to DI for factual accuracy: 8 February 2024

Report returned from DI: 22 February 2024 (no comments)

Final report issued: 23 February 2024

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: 21 May 2025

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.