Inspection report on compliance with HTA licensing standards
Inspection date: **11 July 2023 (site visit)**

Swansea University
HTA licensing number 12389

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
Swansea University	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 Swansea University ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Governance and quality systems, related to 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 shortfall 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.	The establishment's risk assessments did not reflect all identifiable risks, or cover all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. For example: • The establishment had not assessed all risks associated with the possibility of receiving bodies, or retaining prosections, without appropriate consent. • The establishment had not documented its assessment of the risks associated with its human tissue data storage and back-up arrangements. • Risk assessment 014 noted that '*Regular formaldehyde gas monitoring is carried out by the technicians to ensure the work area complies with legal limits*'. As bodies and parts are ethanol-fixed rather than formalin-fixed, and the establishment had installed a new forced air ventilation system, a decision had been made that formaldehyde gas monitoring would no longer be carried out. This decision had not been documented and the risk assessment had not been updated.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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.	GQ1(a)	Overall, the establishment had a comprehensive suite of documented policies and procedures. To improve these further, and fully reflect current practices, the DI is advised to ensure they cover the processes described by establishment staff for: • manually recording the daily refrigerator temperatures; • checking donor consent forms when collecting embalmed bodies, or the process for seeking confirmation of appropriate consent after the body has been collected; • confirming with the loaning HTA- licensed establishment that donor consent is in place to retain prosections once the body has been returned; and • responding to alarms out of hours.
2.	GQ1(a)	Documentation refers to two establishments which may loan bodies and prosections for teaching, and to which bodies and relevant material may be returned. At the time of the inspection, agreements were in place with only one of the establishments. The DI is advised to update documentation accordingly.
3.	GQ2(a)	The DI is advised to increase the scope of internal audits to ensure they provide an assurance that

		consent is in place for all bodies and prosections. Internal audits should also include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. In addition, to provide greater assurances on security, the DI is advised to include audits of security measures and facility access records

Background

Swansea University Medical School is a facility that provides teaching of human anatomy to undergraduate and postgraduate students, and physician associates. The establishment receives embalmed bodies and prosections under an agreement from another HTA-licensed establishment, and also produces prosections onsite.

Swansea University has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent being a Virtual Regulatory Assessment which took place in May 2021.

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

38 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)), standards relating to consent training (C2(a), C2(b) and C2(c)), and standards related to disposal (T2(a) and T2(b)) were not applicable as the establishment does not directly seek consent from donors, or dispose of material.

Review of governance documentation
Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing staff training, adverse events, incidents, governance meetings, agreements with the establishments providing embalmed bodies and prosections, and audits were also reviewed.

Visual inspection
The inspection included a visual inspection of the anatomy suite including the areas where staff receive and store embalmed bodies, prosections and relevant material, and the areas where relevant material and anatomical specimens are used for training, anatomical examination, and dissection.

Audit of records
An audit was undertaken of records and labelling for one embalmed body in the storage area, three prosections (one stored in fluid and two refrigerated), one potted specimen, and one set of skeletal material. There was full traceability for all material.

Meetings with establishment staff
The inspection included discussions with the DI (an anatomist), two anatomists, and other anatomy staff carrying out processes under the licence.

Report sent to DI for factual accuracy: 1 August 2023

Report returned from DI: 2 August 2023

Final report issued: 2 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: 30 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.