Licence application assessment report on compliance with HTA licensing standards
Site visit date: **03 August 2022**

University of Chester
Proposed HTA licensing number 12740

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

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
University of Chester	Applied to be licensed	Not applied to be licensed	Applied to be licensed	Applied to be licensed

Summary of findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

The University of Chester (the establishment) was found to have met all HTA standards.

Advice

The HTA advises the proposed DI to consider the following to further improve practices:

Number	Standard	Advice
1.	GQ2(a)	The establishment has an internal audit plan and SOP covering all licensable activities. As the dates for specimen delivery have not yet been confirmed, the audit schedule is not finalised. After these dates have been confirmed, the proposed DI is advised to add specific dates to the schedule to ensure audits are carried out in accordance with the intended timelines.
2.	GQ6(a)	Although a comprehensive and appropriate range of risks has been assessed in the 'Anatomical Specimens for Education and Training General Risk Assessment', some risk assessments would benefit from an alignment in approach at next review. For example, 'security arrangements' have been identified as a hazard when, more typically, they might be expected to be considered a mitigation.
3.	PFE1(b)	The premises are secure, with access restricted to anatomy staff only. The proposed DI may wish to have a system in place to formally review records of swipe card access to the specimen storage area to confirm that access events are consistent with expectations.
4.	N/A	There are no proposed Persons Designated (PDs) named on the licence application. The proposed DI is advised to consider adding PDs who can assist them in ensuring compliance with the legal and regulatory requirements.

Background

The University of Chester (proposed licensing number 12740) is a new anatomy teaching centre within an existing medical school which has been developed as part of a new graduate entry medical programme, and as an enhancement of anatomy teaching on other programmes delivered at the University. They have applied for a HTA licence in the anatomy sector to cover the carrying out of an anatomical examination, the storage of an anatomical specimen and the storage of a body of a deceased person (or relevant material from a body) for use for a scheduled purpose.

Description of activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the visit:

Standards assessed against during visit

38 out of 47 HTA licensing standards were covered during the visit (standards published 3 April 2017). All standards relating to consent including C1(a), (b), (c), (d), (e) and (f) and C2(a), (b) and (c) were not applicable as the establishment are importing all specimens and does not intend to directly seek consent from donors.

Review of governance documentation

A full document review was completed, covering policies, the overarching quality manual and standard operating procedures relating to licensable activities. Documented security arrangements, audit documents, risk assessments, incidents reporting procedures and staff training plans were also assessed.

Visual inspection

The licence assessment included a visual inspection of the premises and included the anatomy suite, all entrances, the student store room, teaching rooms, clinical rooms and the specimen store room where the cabinets are located.

Meetings with establishment staff

Virtual and in-person meetings were held with staff that will be carrying out processes under the licence, including the new Head of Anatomy (and proposed DI), the Medical School Project Manager and the Executive Dean of the faculty.

Report sent to proposed DI for factual accuracy: 16 August 2022

Report returned from proposed DI: 17 August 2022

Final report issued: 18 August 2022

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 site visit 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, or;
   - 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 site visit.

   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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.