Licence application assessment report on compliance with HTA licensing standards
Site visit date: **22 March 2023**

Aston University

Proposed HTA licensing number

12753

Application for a licence under the Human Tissue Act 2004

Activities applied to be licenced

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
Aston University	Applied to be licensed	Not applied to be licensed	Not 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.

Although the HTA found that Aston University (the establishment) had met the most of the HTA's standards, five minor shortfalls were found against standards for Governance and quality systems and for Traceability. These related to standard operating procedures (SOPs), risk assessments, traceability of parts in storage and documenting disposal.

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 site visit.

Compliance with HTA standards

Minor Shortfalls

GQ1 All aspects of the establishment's work are supported by ratified 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.	SOPs did not contain comprehensive information to enable a member of staff to follow a process from beginning to end. The establishment plans to receive wet specimens from another HTA-licensed establishment but there was no SOP for the receipt procedure. "The establishment submitted sufficient evidence to address this shortfall before the report was finalised."	**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.	The establishment had not carried out any risk assessments for the practices and processes that require compliance with the HT Act and HTA's Codes of Practice. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	At the time of the assessment, the establishment had started to add unique codes to anatomical parts in storage; however, this process had not been completed and a large proportion of relevant material did not have a unique code assigned to it. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
b) A register of donated material, and the associated products where relevant, is maintained.	The inventory of stored material was not in a format that enabled full traceability of specimens or parts from storage through to use and disposal. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and method used are documented.	The Disposal SOP and disposal form did not include the requirement for recording the reason and method for disposal. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The prospective DI is advised to review all SOPs and consider whether they could be made easier to follow by staff; for example, being presented in a step-wise format, with numbered paragraphs.

2.	GQ1(a)	The establishment plans to receive wet specimens from another HTA-licensed establishment after the licence is granted. These may need to be topped up with preservation fluid, containing formaldehyde. The prospective DI is advised to develop procedure/s to support the management and use of these specimens, including health and safety considerations.
3.	GQ1(b)	Although the majority of documents were controlled, it was noted during the assessment that some documents did not have a version number and issue date. The prospective DI should consider reviewing all documents to ensure that these are all part of the document control system.
4.	GQ2(a)	The prospective DI may wish to develop an audit proforma to enable audits to be undertaken using a consistent approach.
5.	GQ2(a)	The establishment has an internal audit SOP in place which describes the audit types that will be undertaken. The prospective DI should consider adding observational audits of staff undertaking activities to ensure they take place in accordance with SOPs.
6.	GQ5(a)	The prospective DI should consider adding examples of types of adverse events to the Adverse Event Reporting SOP and consider documenting the process for managing incidents and their closure. This will help to ensure all staff are aware of the types of incidents that could occur and how they will be managed.
7.	T1(g)	The establishment plans to use the due diligence form used under the governance arrangements for the Research sector licence. This form is is completed before samples are received into the establishment to ensure that the samples conform to the requirements set out by the establishment. The prospective DI should review this form and make any adjustments to ensure that is reflective of the checks that need to be in place before receiving material under the governance of the Anatomy sector licence.
8.	PFE2(c)	The prospective DI is advised to formalise, in advance, the planned approach to formaldehyde monitoring after the proposed new wet specimens are received into the establishment. This is to ensure that the levels of formaldehyde maintained within normal limits.

Background

Specimens were being stored for use in education and training under the Research sector licence held by the establishment (licensing number, 12381). All material stored under the governance of the Research sector licence was either over 100 years old or classified as an existing holding, including some previously imported specimens.

An application for an Anatomy sector licence was made in January 2023 and this report describes the findings after initial remote assessment and following a site visit.

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

All 47 standards were assessed (standards published 3 April 2017).

Review of governance documentation

Key policies and procedural documents relating to licensed activities were reviewed. These included SOPs relating to receipt, storage, use and disposal of cadaveric material, material transfer agreements and an inventory of material stored.

Visual inspection

A visual inspection of the storage area where specimens are stored was carried out. The facility has privacy glass, so staff or visitors cannot see into the clinical laboratory areas where anatomy teaching will take place. The room remains locked, with the key accessible only to limited members of staff. As part of the visual inspection, the Lead Inspector reviewed the process for adding the unique codes to the specimens. The specimens are stored in airtight containers in a designated storage cupboard.

Meetings with establishment staff

A meeting was held with the prospective DI, the DI for the Research licence and three Anatomy lecturers.

Report sent to proposed DI for factual accuracy: 12 April 2023

Report returned from proposed DI: 16 June 2023

Final report issued: 19 June 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 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.