Inspection report on compliance with HTA licensing standards
Inspection date: **19 September 2023**

Aston University

HTA licensing number 12381

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Aston University	Licensed	Not 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.

Aston University was found to have met all HTA standards.

Advice

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

Number	Standard	Advice
1.	GQ1(a)	At the time of the assessment licensable storage was limited, with only 21 tumour tissue samples being stored under the licence. These samples originated from a HTA-licensed tissue bank and there were no plans to receive any further samples. These stored samples had not been processed or used in laboratory experiments. The DI should ensure that appropriate procedures for the preservation of tumour samples are in place before laboratory activities commence.
2.	GQ2(a)	The DI should consider reviewing the approach to auditing, including whether it may be beneficial to involve research principal investigators or Persons Designated to support the audit function. At present this responsibility sits with the DI only - including a wider pool of staff to support the DI may be helpful.
3.	GQ2(b)	Although the majority of tissue is stored under the governance of an NHS ethical approval, the DI should consider developing an audit proforma which can be used to record audit findings and also actions arising from audits. This will help to provide consistency in approach.
4.	GQ3(a)	At the time of the VRA the DI had developed a proforma for recording staff competency before working with human tissue. To improve the quality of the audit trail, the DI should consider recording the date and signature of the assessor and the trainee, for when the trainee was deemed competent.

5.	GQ5(a)	The DI is advised to review HTA's licensing standards guidance and consider adding practical examples to the adverse event procedure so that staff have an understanding of the types of events which could occur and how these are to be managed.
6.	T1(c)	The 'DI approval process' extends to all research involving human tissue at the University. It is a robust process which enables the DI to keep a register of active research where human tissue is stored under licence or NHS REC approval. Although the register has been subject to regular review, the DI flagged that it had not been updated recently. The DI is advised to ensure that a regular review is carried out so that the information remains accurate.
7.	PFE2(c)	To improve staff awareness, especially helping to identify any issues when accessing human tissue stored in the freezers, the DI should consider adding signage which details the lower and upper temperature limits that trigger an alarm.

Background

The establishment is a University and this was the second inspection of the establishment; the most recent previous inspection took place in March 2015. At the time of the assessment, the University was storing a limited number of human tissue samples under the governance of the HTA licence, with the vast majority of studies storing under the governance of an NHS Research Ethics Approval or storing acellular material.

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

46 HTA licensing standards were covered during the inspection (standards published 3 April 2017). PFE2(b) was not applicable as the establishment does not store material from the deceased.

Review of governance documentation

Key documents were reviewed, including, policies and procedural documents relating to licensed activities, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records.

Audits

The DI provided evidence of audits that had been undertaken of research studies where human tissue is stored under the governance of NHS REC approval. The DI also provided evidence that an audit had been carried out of the 21 tumour tissue samples in storage at the time that the samples were received by the establishment. No further audits had been undertaken as this was a static collection.

Meetings with establishment staff

Round table discussions with the DI, Corporate Licence Holder contact (CLHc) and Persons Designated (PDs) took place.

Report sent to DI for factual accuracy: 3 October 2023

Report returned from DI: 10 October 2023 (with comments)

Final report issued: 11 October 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.