Inspection report on compliance with HTA licensing standards
Inspection date: 11 February 2022

Durham University

HTA licensing number 12382

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
Hub site **Durham 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.

Although the HTA found that Durham University ('the establishment') had met the majority of the HTA's standards, five minor shortfalls were found against standards for Consent and Governance and quality systems.

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

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The current audit schedule comprises a single annual audit against a small number of HTA standards, which does not provide satisfactory assurance that the establishment is able to demonstrate compliance with our standards or is meeting the requirements of its own systems.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
d) Staff have appraisals and personal development plans.	There was no evidence that staff working under the licence have regular appraisals or personal development plans.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	At the time of the inspection, many paper-based records, including traceability records, were not backed-up.	**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.	Some documented risk assessments do not contain adequate details of identified mitigating actions, meaning that they provide only limited assurance.	**Minor**
b) Risk assessments are reviewed regularly.	Risk assessments are not reviewed regularly.	**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.	GQ1(a)	The DI is advised to review policies and SOPs to ensure that the current HTA Standards and Codes of Practice (A and E) are referenced.

2.	GQ1(c)	A new, electronic system is being introduced to centralise all records. The DI is advised to ensure there are change control mechanisms for the implementation of new operational procedures resulting from this new system. These should include how paper-based and electronic records, which are currently stored locally, will be transferred to the new system.
3.	GQ2(a)	The DI is advised to increase the frequency and scope of auditing activities to include the auditing of records, and vertical and horizontal audits. This will provide greater assurances to the DI that the establishment can demonstrate compliance with our standards and demonstrate it is meeting the requirements of their own systems
4.	GQ6(a)	The DI is advised to include in - all risk assessments - an evaluation of the level of the risk, the mitigating actions identified and the level of residual risk remaining. If an SOP is referenced as a mitigating action, the DI is advised to identify the specific step/s in the SOP to ensure the mitigating action is documented clearly.
5.	PFE2(c)	Critical storage units are monitored, and a remote call-out system is in place to alert key staff when there is a failure of storage conditions. In line with our published standars guidance, the DI is advised to manually challenge this system periodically to ensure the procedure is operating as expected, and to document this.
6.	PFE3(a)	Critical storage units are subject to maintenance on an ad hoc basis. The DI is advised to implement a maintenance schedule as recommended by the manufacturer and document when maintenance has been performed.

Background

Durham University has been licensed by the HTA since 2007. This was the second inspection of the establishment; the previous inspection took place in June 2011.

Since the previous inspection, the satellite licence at Queen's Campus, Stockton-on-Tees was revoked in 2015 and there have been changes to key people working under the licence including the Designated Individual in 2020 and the Corporate Licence Holder contact in 2017.

Relevant material is stored for the scheduled purpose of research in connection with disorders, or the functioning, of the human body in the Schools of Biological and Biomedical Sciences, Psychology,Engineering and Physics. Relevant material is stored for the scheduled purpose of education or training relating to human health in the Department of Biosciences and Anthropology.

Two research groups in the Psychology Department are seeking consent from donor volunteers at the University for projects that have received approval from Durham University Departmental Ethics Committee. Samples from three other research groups stored under the HTA licence have been obtained from other UK establishments or have been imported from outside the UK. Material Transfer Agreements provide assurances that appropriate and valid consent for research has been obtained. Two research groups are storing samples for projects under current NHS Research Ethics Committee (REC) approval, which are exempt from HTA licensing.

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

Standard PFE2(b) was not applicable to the current activities undertaken by the establishment. All remaining 46 licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to all licensed activities, consent documentation, standard operating procedures and documents relating to traceability systems. Documents detailing staff training, adverse events, incidents, governance meetings, risk assessments and audits were also reviewed.

Visual inspection

There was no site visit inspection associated with the inspection.

Meetings with establishment staff

The assessment included discussions with staff working under the licence. This included a consent seeker, Persons Designated, the Human Tissue Board Secretary, and the DI.

Report sent to DI for factual accuracy: 7 March 2022

Report returned from DI: 18 March 2022

Final report issued: 24 March 2022

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 Virtual Regulatory Assessment Report.

Date: 4 July 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 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.