Inspection report on compliance with HTA licensing standards
Inspection date: **14 October 2022**

University of Huddersfield

HTA licensing number 12641

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
University of Huddersfield	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.

The University of Huddersfield ('the establishment') was found to have the met most of HTA's standards; however, seven minor shortfalls were identified against standards for Governance and quality systems and Premises, Facilities and Equipment (to insert).

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 assessment.

Compliance with HTA standards

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures as part of the overall governance process		
GQ1(a) Ratified, documented and up-to-date policies and procedures are in place covering all licensable activities	The documented procedures linked to the Biobank lack detail and the full range of steps that enable a member of staff to undertake the activity.	**Minor**
GQ1(b) There is a document control system	The establishment does not have a document control system in place to manage procedures relating to HTA licensable activities and there is no consistent review cycle length in place.	**Minor**

GQ2 There is a documented system of audit		
GQ2(a) There is a documented schedule of audits covering licensable activities	The establishment has not conducted regular audits and there is no documented schedule of audits in place.	**Minor**

GQ6 Risk assessment of the establishment’s practices and processes are completed regularly, recorded and monitored		
GQ6(b) Risk assessments are reviewed regularly	The risk assessments are not subject to a regular cycle of review.	**Minor**
GQ6(c) Staff can access risk assessments and are made aware of risks during training	The risk assessments are not widely available to staff carrying out licensable activities.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
PFE2(c) Storage conditions are monitored, recorded and acted on when required	The -80C freezers are not monitored using a continuous electronic or manual monitoring temperature system. There is no system in place to enable temperature trends to be reviewed regularly to identify a shift in temperature. Furthermore, the freezer alarms are not tested and there is no provision for a member of staff to be alerted to an excursion out of hours over a weekend or during periods of extended University closure.	**Major**

Advice

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

Number	Standard	Advice
1.	GQ3(b)	The establishment provides induction training for new staff who will be working with human tissue. They are expected to meet the DI where they are given Human Tissue Act Training. The MRC training on consent is also required to be completed by all staff. It was noted during the inspection that one of the researchers who is involved in Biobank activities, though appropriately trained in working with human tissue, did not have a completed Research and Integrity Checklist completed, which is a record of all the training required before working with human tissue. The inspection team noted that this form was introduced recently, however, the DI may wish to consider requesting staff in post prior to the introduction of this form to complete the checklist as part of their training file.
2.	GQ6(a)	The DI may wish carry out a thorough assessment of risk to the tissue stored, in light of the shortfall identified in PFE2(c) to review whether the control measures at present are sufficient.
3.	T1(b)	The DI is advised to review the approach to documenting traceability of tissue slides. Slides are uniquely identified by the experimental approach they have been used in; however, the traceability system does not confirm the number of slides that have been created. The DI may wish to consider including this information as part of the record, so it is easy to identify the number of slides in storage.
4.	PFE2(a)	The DI is advised to label the freezers with the alarm set points as well as instructions on steps to be taken if a critical storage failure should occur.

5.	PFE3(a)	The establishment does not have in place a maintenance contract for the freezers and rely upon technical staff to deal with equipment problems or failures. The DI is advised to consider having in place a maintenance contract to ensure that equipment remains in good working condition.

Background

The establishment is a university, with licensable storage under the Human Tissue Act within the area of Applied Sciences. The establishment stores relevant material, such as skin and hair under the governance of a research tissue bank approval. This material was commercially sourced. At the time of the inspection the establishment was not actively involved in seeking of consent as one of the studies had been placed on hold

Description of inspection activities undertaken

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

Standards assessed against during inspection

Of the 47 HTA standards, 46 were assessed (standards published 3 April 2017). Standards PFE2(b) was not applicable.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff competency records and records relating to traceability.

Visual inspection

There was no site visit; however, the establishment provided a number of photographs of the licensed storage area. This was followed up by a meeting with relevant staff members to discuss the PFE standards.

Audit of records

No traceability audits were carried out. The establishment did not provide evidence of documented audits, although email confirmation was provided that an audit of the Biobank had been carried out informally.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and PDs (Persons Designated).

Report sent to DI for factual accuracy: 9 November 2022

Report returned from DI: 18 November 2022 (no comments)

Final report issued: 21 November 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 Inspection Report.

Date: 5 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 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.