Inspection report on compliance with HTA licensing standards
Inspection date: **21 June 2024**

University of York
HTA licensing number 12604

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 York	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 University of York ('the establishment') was found to have met the majority of the HTA's standards, three minor shortfalls were identified – these were against Governance and quality system (GQ) and Premises, facilities and equipment (PFE) standards.

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

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.	Although there are meetings between the DI and Person Designated (PD), at the time of the inspection there were no formalised governance meetings where licensed activities are discussed.	**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 York tissue bank did not have any risk assessments for activities relating to human tissue storage and use.	**Minor**

PFE1 The premises are secure and fit for purpose		
a) An assessment of the premises has been carried out to ensure they are appropriate for the purpose.	The premises has a back-up generator in the event of power failure, however this does not provide continual power to the building where human tissue is stored. Although the back-up generator is tested regularly, the establishment has not conducted a risk assessment to assess the risk to samples.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Researchers retrieve slides from the URoBank tissue bank archive to use for research purposes. Once a researcher completes their work, the slides are returned to the archive, however, the slides may not always be placed back in the correct location. Tissue bank staff review all slides to locate those that have been returned.

		The DI should consider reviewing the current process for receiving slides, for example, identifying a specific location for researchers to place returned slides.
2.	C1(c)	The DI should consider reviewing the material transfer agreement template to make clear that staff involved in seeking consent must be appropriately trained. This will help provide reassurance to the establishment about the governance arrangements around consent.
3.	GQ2(a)	The DI is advised to consider extending the range of audits to include coverage of processes and procedures, for example staff undertaking a specific task.
4.	GQ3(b)	There are several researchers that collect tissue under the governance of the York Tissue Bank ethical approval. Staff are appropriately trained before they can start collecting tissue. The DI should consider introducing refresher training for researchers to ensure that competencies are maintained.
5.	GQ4(a)	Paper records relating to traceability are backed up electronically on a monthly basis. The DI should consider more frequent back-up arrangements to reduce the risk of loss of records.
6.	GQ6a)	Occasionally, URoBank samples are temporarily stored in a four degrees celsius fridge. This fridge is not temperature monitored, and fridge temperature readings are only recorded by staff before samples are stored. The samples may only be stored for a few hours before they are processed. The DI should consider undertaking a formal risk assessment of this practice to review potential risks to samples stored.
7.	PFE3(a)	The URoBank tissue bank team are responsible for checking the condition of the liquid nitrogen dewar during the weekly fill that is carried out. Although a condition check of the dewar is performed it is not formally

		documented. The DI should ensure that condition checks to the dewar are formally documented to monitor any deterioration over time.

Background

University of York (the establishment) stores human tissue under two research tissue banks; these are URoBank and York Tissue Bank. URoBank samples are collected prospectively from tissue collection centres in the UK. Consent is sought by the clinical teams at the tissue collection centres. The samples are then received by the tissue bank team and processed, with residual samples being stored under the licence.

The York Tissue Bank comprises of samples from a research study which was previously under a recognised research ethics approval. Research studies can be adopted under the York Tissue Bank which enables researchers to collect and store tissue samples under the governance of the Research Tissue Bank ethical approval.

This report describes the second HTA inspection of the establishment.

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, 40 standards were assessed (standards published 3 April 2017). HTA standards, C1(b),(d),(e),(f) and C2(a),(b),(c) were not applicable as the establishment is not directly involved in seeking consent. PFE2(b) is not applicable as the establishment does not store material from the deceased.

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, sample tracking system, temperature monitoring data and incidents.

Visual inspection

There was no visual inspection of the premises however, a meeting took place with relevant staff members to discuss the PFE standards. A powerpoint presentation of the areas where human tissue is stored was shared during the assessment.

Audit of records

No traceability audit was carried out however, a review of recently conducted audits was undertaken as part of the assessment.

Meetings with establishment staff

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

Report sent to DI for factual accuracy: 15 July 2024

Report returned from DI: 19 August 2024 (with comments)

Final report issued: 20 August 2024

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: 3 December 2024

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.