Inspection report on compliance with HTA licensing standards
Inspection date: **12 February 2025**

Brunel University of London

HTA licensing number 12543

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
Brunel University of London	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 Brunel University of London ('the establishment') was found to have met the majority of the HTA's standards, five minor shortfalls were identified against Consent and Governance and quality system standards. These shortfalls related to consent training, documentation of procedures for seeking consent, consent training, managing actions following audits, risk assessments relating to licensable activities and storage conditions.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	There was no documented consent procedure for research that involved seeking consent from healthy volunteers.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a)There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA'S Codes of Practice	During the inspection, a research collection where samples are stored from healthy volunteer participants was reviewed. There was no evidence that consent training, which addresses the requirements of the HT Act, had been given to staff involved in seeking consent.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings include who will be responsible for follow-up actions and the timeframes for completing these	There was no system to record actions arising from audits.	**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	Risk assessments are undertaken by each research group before they can commence collecting or storing human tissue at the establishment. Although some groups had assessed risks relevant to licensable storage, others had only undertaken health and safety risk assessments.	**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's fridges and -20^{0}C freezers are not on the continuous monitoring system and there was no related risk assessment covering the risks to stored tissue with reference to these arrangements.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment has developed consent form templates. These would not allow samples to be stored or used for future research without further consent being sought. The DI is advised to review these templates and consider whether it could be useful to include an option for a participant to provide consent for future research.
2.	GQ1(a)	The establishment stores tissue slides which have historically been used in teaching. If this activity is to be resumed, the DI should develop a documented procedure which contains information on how the resource should be accessed, used and managed.
3.	T1(b)	There was no central register of human tissue stored under projects with recognised Research Ethics Committee (REC) approval and human tissue stored under licence. Whilst the number of projects at the establishment is limited, the DI should consider keeping a register of studies and their expiry dates so it is clear which studies fall under licence and which fall under a licensing exemption

4.	T1(c)	The DI is advised that where a participant does provide consent for long term storage of human tissue for undefined future research, that the sample tracking system is updated to reflect this. This will help to ensure that sample tracking system remains up-to-date and accurate.
5.	PFE2(c)	The establishment has continuous temperature monitoring for some freezers and carries out some manual monitoring of others. The manual temperature monitoring is recorded once each week. The DI should consider carrying out more regular temperature checks to help identify when storage conditions may be deteriorating and to alert staff to developing equipment failure.
6.	PFE2(c)	The DI is advised to carry out regular alarm testing to ensure that the alarm notification system is working as expected.

Background

The establishment is a University and stores human tissue for research under the governance of their HTA licensing arrangements and under approvals from recognised research ethics committees. There is a local university ethics committee that approves each research study which will involve the storage of human tissue. The establishment is also involved in seeking consent from healthy volunteers from whom blood is collected and stored for research. The establishment only stores material from living donors.

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

Of the 47 HTA standards 46 were assessed (standards published 3 April 2017). PFE2(b) is not applicable as the establishment does not store human tissue from deceased donors.

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, incident reports and material transfer agreements.

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 presentation was provided, which included photographs of areas where licensed storage takes place.

Audit of records

No traceability audit was carried out; however, a review of recent audits conducted for some research groups was undertaken as part of the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Technical Manager, Facilities Manager and academic research staff involved in working with human tissue.

Report sent to DI for factual accuracy: 7 March 2025

Report returned from DI: 31 March 2025 (no comments)

Final report issued: 2 April 2025

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.