Inspection report on compliance with HTA licensing standards
Inspection dates: **05 and 27 August 2025**

University of Southampton
HTA licensing number 12009

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 Southampton	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 University of Southampton ('the establishment') had met the majority of the HTA's standards, seven minor shortfalls were found against standards for Consent, Governance and quality systems, and Premises, facilities and equipment.

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 were several discrepancies found in the consent processes and associated consent documents. • One of the establishment's research tissue banks (RTBs) was storing a limited number of samples for which consent had been obtained from the deceased donor's 'next of kin'. For two donors, the person who gave consent in each case was a child of the donor but there was no record to demonstrate that consent had been sought from a person accorded the highest ranking in terms of the qualifying relationships set out in section 27(4) of the Human Tissue Act 2004. • One of the establishment's research tissue banks held a collection of human material which had no evidence of consent for future storage of samples. The signed consent forms and accompanying patient information sheets had no references to storage and use of samples for research beyond the duration of the study. • Other collections had consent records which were found to have missing elements, including signatures of consent-seekers, dates, and pages.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained.	Not all consent-seekers had undergone competency assessments to demonstrate proficiency in consent-seeking in accordance with the requirements of the Human Tissue Act 2004 and HTA's Codes of Practice.	**Minor**
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The overarching HTA Standard Operating Procedure (SOP) did not cover all the licensed activities in the four research tissue banks under the licence. Some procedures being carried out in specific areas had different processes and were not in accordance with this SOP. Additionally, these specific procedures were not supported by ratified, documented, and up-to-date SOPs.	**Minor**
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.	There were no governance meetings held in the last year to support HTA-related activities and to enable staff working under the licence to be aware of the governance arrangements in place.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	No internal audits had been undertaken since 2019 on all four research tissue banks.	**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.	Not all research tissue banks had documented risk assessments for their associated licensed activities. A documented risk assessment was in place in one tissue bank but did not cover key practices and processes involved with other collections under the licence.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	Each of establishment's research tissue banks had emergency storage facilities identified and allocated but not all of them had documented contingency plans in place for staff to follow to preserve the integrity of the HTA relevant material in case of failure in storage area.	**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.	T1(c)	The establishment maintained a comprehensive audit trail of samples held under the licence. However, in some collections, several samples were kept in one container without a defined order of placement within the storage compartment. The DI is advised to consider implementing a more structured cataloguing scheme within storage containers to enable systematic identification of specific sample locations.

2.	PFE2(c)	The establishment had robust temperature monitoring and alarm systems. However, alarm tests were only routinely performed in one tissue bank. There were no regular alarm tests carried out on the rest of the other storage facilities. The DI is advised to establish regular temperature alarm testing and periodic manual challenge in all critical storage areas to ensure systems are operating as expected.
3.	PFE3(b)	A system for reporting equipment failure was in place and was supported by an SOP for one of the research tissue banks. There were no similarly-defined processes for reporting equipment problems in the other biobanks. The DI is advised to ensure consistency for equipment failure reporting procedures in all areas operating under the licence.

Background

The University of Southampton stores relevant material in four separate research tissue banks that have broad ethical approval from recognised research ethics committees: Cancer Sciences, Southampton Research Biorepository, Respiratory, and Eye tissue banks. The establishment has been licensed by the HTA since March 2007. This was the third inspection of the establishment; the most recent inspection was a routine site visit which took place in April 2018. Since the previous inspection, the establishment has appointed a new Corporate Licence Holder contact (CLHc) and two Persons Designated (PDs).

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

46 of 47 HTA licensing standards were covered during the licence assessment (standards published 3 April 2017). PFE2(b) was not relevant as the establishment does not store deceased donors.

Review of governance documentation
A number of documents were reviewed during the assessment which included policies and SOPs relating to licensed activities, consent forms and donor information sheets, material transfer agreement (MTA) templates, risk assessments, meeting minutes, reported incidents, temperature monitoring for the storage units, records of servicing, and staff training records.

Visual inspection
No visual inspection was undertaken as part of this inspection. However, a meeting took place with relevant staff members to discuss compliance with the Premises, facilities and equipment (PFE) standards. Digital images of freezers and Liquid Nitrogen storage facilities were viewed remotely.

Audit of records
Traceability audits were carried out remotely for samples stored for eight collections held under the licence. The audits included a variety of samples, stored in different conditions, taken from living and deceased donors. Traceability details were cross-checked between the identification details on the samples, information on the electronic and paper records and the associated consent forms. Audits were also carried out for samples disposed of after use. All samples audited were traceable.

Meetings with establishment staff
Roundtable discussions were carried out with establishment staff which included the DI, lead and other PDs, Quality Managers, Quality Assurance Officer, Tissue Bank Technician, Technical Manager, and various PDs.

Report sent to DI for factual accuracy: 18 September 2025

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 02 October 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.