Inspection report on compliance with HTA licensing standards
Inspection date: **23 April 2025**

Leicester Royal Infirmary

HTA licensing number 12384

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
Leicester Royal Infirmary	Licensed	Not licensed
Satellite site University of Leicester	Licensed	Not licensed
Satellite site Glenfield General Hospital	Licensed	Not licensed
Satellite site Leicester General Hospital	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.

Leicester Royal Infirmary ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

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

Number	Standard	Advice
1.	GQ1(a)	Some of the establishment's documents have not been updated to reflect the change in DI. The DI is advised to ensure that all relevant policies and procedures are reviewed, ratified, and updated to include his name.
2.	GQ1(a)	The establishment's SOPs are reviewed regularly. However, those that remain unchanged are not re-circulated to staff. The DI is advised to consider re-distributing active SOPs periodically, even when no changes have been made, to support staff awareness and to refresh their understanding of current procedures.
3.	GQ2(a)	The establishment holds a large number of collections across the hub and three satellite sites. While internal audits are conducted by the establishment's HTA Monitor, Persons Designated (PDs) also conduct regular 'mini audits'. The DI is advised to consider expanding these mini audits to include each PD's full collection. This would support the identification of issues across the full scope of holdings and increase awareness of any historical collections that may need to be brought under the licence.

4.	GQ4(a)	A large number of the establishment's HTA SOPs are marked as version 2.0; however, version 1.0 of these documents cannot be clearly traced, and the changes made were not recorded in the review history. The DI is advised to update the SOPs' review histories to include references to superseded versions and use them to clearly document a note of amendments made, to ensure a transparent and auditable record of document changes.
5.	GQ6(a)	Review of internal audit reports indicated that several findings were associated with changes in study team personnel. The DI is advised to include potential risks to study continuity—such as staff turnover—in relevant risk assessments, and to implement appropriate control measures to minimise their impact on ongoing studies.
6	N/A	The establishment's core governance activities are led by the University of Leicester, which is also the corporate body that holds the licence. To ensure that the licence accurately reflects current governance arrangements, the DI is advised to consider submitting a licence variation to designate the University of Leicester as the hub site and the Leicester Royal Infirmary as a satellite site.

Background

The establishment has five Research Tissue Banks (RTBs): Respiratory, Haematology, Sarcopenia, and two Cancer RTBs. The establishment has been licensed by the HTA since November 2006. This was the fifth inspection of the establishment. A previous site visit inspection took place in June 2019 and an Evaluated Self-Assessment (ESA) was undertaken in August 2023. Since the previous inspection, the establishment has appointed a new DI in December 2024.

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
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, traceability audits, 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. Fridges, freezers, and Liquid Nitrogen storage facilities were assessed remotely through photographs and recorded video tours.

Audit of records
No traceability audit was carried out. However, a review of recent audits conducted for several research groups was undertaken as part of the assessment.

Meetings with establishment staff
Roundtable discussions were carried out with establishment staff which included the DI, HTA Monitor, and Director of Operations for College of Life Sciences, Trial Manager, Tissue Bank Manager, and various PDs.

Report sent to DI for factual accuracy: 07 May 2025

Report returned from DI: 16 May 2025

Final report issued: 21 May 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.