Inspection report on compliance with HTA licensing standards
Inspection date: **8 September 2026**

King's College London

HTA licensing number 12293

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
King's College 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 HTA found that King's College London ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against Consent and Governance and quality systems standards. These related to an outdated consent policy and gaps in the establishment's risk assessments.

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.

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 code 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	The '*Policy on Consent for Use and Storage of Human Relevant Material for a Scheduled Purpose'* was found to be overdue for review and contained references to superseded HTA Codes of Practice.	**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	For some collections held under the licence, risk assessments had not identified all significant risks associated with the licensed activities, for example risks relating to consent.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The establishment has a robust audit programme covering a wide range of HTA-related activities. To provide further assurance regarding compliance with consent requirements, the DI is advised to extend the audit programme to include review of consent documentation. By way of example, audit activities could be used to verify that appropriate consent forms are present, completed correctly, and retained in accordance with establishment procedures and HTA requirements.
2.	GQ2(b)	Audit findings indicate that, for the Haematology research tissue bank, samples have repeatedly been received

		without the accompanying consent documentation. Although these instances are logged appropriately and managed, the DI is advised to consider providing further training and reinforcement of procedures to those supplying samples. This will help reduce the risk of relevant material being stored without adequate evidence of consent.
3.	GQ4(c)	When reviewing the '*Policy on Consent for Use and Storage of Human Relevant Material for a Scheduled Purpose* (identified in the shortfall under C1(a)), the DI is advised to update references to the superseded Data Protection Act to ensure references to legislation are current and accurate.

Background

King's College London has been licensed by the HTA since November 2007. This was the third inspection of the establishment; the most recent assessment was an Evaluated Self-Assessment (ESA) and took place in August 2023.

Since the previous inspection, there have been no significant changes to the licence arrangements.

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

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures (SOPs) were reviewed. Documents detailing internal audits, risk assessments, meeting minutes, incidents and staff training were also reviewed.

Visual inspection

There was no site visit inspection associated with the assessment although images of the premises, facilities and equipment were reviewed.

Audit of records
There was no site visit associated with this assessment; however, the establishment's internal audit reports were reviewed.

Meetings with establishment staff
The assessment included meetings with the Laboratory Manager, Persons Designated for each of the collections and Biobanks, the Manager of the Brain Bank (who holds the position of DI) and the Head of Biobanking (who holds the position of Corporate Licence Holder contact).

Report sent to DI for factual accuracy: 2 October 2026

Report returned from DI: 8 October 2026

Final report issued: 9 October 2026

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.