Inspection report on compliance with HTA licensing standards
Inspection date: **16 September 2026**

UCL Queen Square Institute of Neurology

HTA licensing number 12198

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
Hub site **UCL Queen Square Institute of Neurology, WC1N 3BG**	Licensed	Not Licensed
Satellite site **UCL Institute of Neurology, Wakefield Street, WC1N 1PJ**	Licensed	Not Licensed

Satellite site **UK Dementia Research Institute at UCL, Gower Street, WC1E 6BT**	Licensed	Not Licensed
Satellite site **MRC Prion Unit at UCL, Courtauld Building, W1W 7FF**	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 the UCL Queen Square Institute of Neurology (‘the establishment’) had met the majority of the HTA’s standards, two minor shortfalls were found against standards for Consent and Governance and quality systems.

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 shortfall identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained.	While the Queen Square Brain Bank had implemented a two-stage observational approach to assess the competency of staff seeking consent on behalf of the establishment, competency assessments were not routinely undertaken for staff performing similar roles within the other biobanks.	**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	At the time of the inspection, not all of the establishment's practices were governed by documented and up-to-date procedures and policies. Examples included an incomplete consent policy and auditing procedure within the Queen Square Brain Bank (e.g., QSBB 1037), as well as outdated and unclear procedures relating to consent and the release of samples within the Centre for Neuromuscular Diseases Biobank (e.g., SM15). *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The three biobanks operating under the licence have established independent governance arrangements and systems to ensure compliance with the HTA's standards. To strengthen oversight and support ongoing compliance, the DI should consider reviewing these arrangements to identify any gaps, facilitate the sharing of good practice, and, where appropriate, harmonise core elements of the governance framework across the biobanks. This could include, for example, implementing a coordinated programme of reciprocal audits, whereby staff from each biobank routinely review the holdings and processes of the other biobanks, as well as establishing consistent approaches to staff training and competency assessments.
2.	GQ1(e)	The Trust and University have overarching complaints policies and procedures in place. The DI is advised to document how complaints relating to HTA-licensable activities, including those raised by staff, students or researchers receiving material, are managed and escalated under these arrangements.
3.	T1(c)	At the time of the inspection, two satellite sites - the UK Dementia Research Institute and the MRC Prion Unit - were storing relevant material solely under project-specific approvals from recognised Research Ethics Committees (RECs). Ethical approvals are monitored centrally, and end-of-study arrangements are coordinated by the Joint Research Office. Currently, the DI does not have direct oversight of these arrangements. The DI should consider whether the current reporting structure provides adequate assurance and oversight of these and other REC-approved studies, and assess the risk that relevant material could remain on the premises after REC approval has expired without their knowledge or authorisation.

Background

University College London is the Licence Holder for five HTA research sector licences. HTA licensing number 12198 was first issued in 2007, and this was the third inspection, with the last inspection having been undertaken in July 2023. Since the last inspection, the Corporate Licence Holder contact (CLHc) has changed once. At the time of inspection, three main research tissue banks were operating under the licence, encompassing several smaller tissue banks and research collections. The main biobanks were the MRC Centre for Neuromuscular Diseases Biobank London, which did not hold current generic approval from a recognised REC, the Queen Square Brain Bank for Neurological Disorders (REC reference 23/LO/0044), and the Epilepsy Society Brain and Tissue Bank (REC reference 23/SC/0002). The establishment confirmed that all other relevant material was stored under project-specific REC approvals.

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

During the assessment, a range of documents were examined, including audit reports, meeting minutes, overarching University and Trust policies, and local policies and procedures. Other documents reviewed included sample release and transfer agreements, risk assessments, consent templates, participant information sheets, maintenance records and staff training records.

Visual inspection

No site visit was undertaken as part of this inspection. The establishment provided photographs demonstrating access points, security arrangements, and storage facilities at the hub site, which accommodates both the Centre for Neuromuscular Diseases and the Epilepsy Society Brain and Tissue biobanks, as well as at the UCL Institute of Neurology satellite site, which houses the Queen Square Brain Bank. At the time of the inspection, the remaining two satellite sites were storing relevant material solely under project-specific REC approvals. Discussions with the establishment staff covered key operational areas, including contingency storage arrangements, temperature monitoring, equipment maintenance, and the provision and

use of personal protective equipment. The establishment also provided temperature monitoring and maintenance records for three freezers located across the hub and satellite site.

Audit of records
Several audits conducted by the establishment's staff were reviewed, including those relating to the HTA's standards and sample traceability. Staff also demonstrated the systems used to manage audit findings and adverse events, as well as those used to maintain sample registers and records associated with, for example, consent, sample receipt, and sample release.

Meetings with establishment staff
The inspection included discussions with the DI, Persons Designated, Biobank technicians, Laboratory Manager, and a Biobank Co-ordinator.

Report sent to DI for factual accuracy: 24 September 2026

Report returned from DI: 8 October 2026

Final report issued: 22 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.