Inspection report on compliance with HTA licensing standards
Inspection date: **25 July 2023 (remote assessment) and 26 July 2023 (site visit)**

University College London

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 **University College London**	Licensed	Not licensed
Satellite site **MRC Prion Unit at UCL**	Licensed	Not licensed
Satellite site **UK Dementia Research Institute at UCL**	Licensed	Not licensed

Satellite site **UCL Institute of Neurology**	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 College London (UCL) ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems and traceability..

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		
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The Epilepsy Society Brain and Tissue Bank's (ESBTB) 'Post-Mortem Next of kin donor consent' form referred to the term 'next of kin' (NOK) and did not reflect a suitable person in the hierarchy of qualifying relationships under the Human Tissue Act 2004 (HT Act). Supporting information did not include the relationships that would qualify to give consent, including the information sheet provided to the family.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.	There was no records management policy setting out the retention period for records relating to the biobank, including donation records.	**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.	At the time of the inspection, risk assessments for the Queen Square Brain Bank for Neurological Disorders and the ESBTB biobank were limited in scope and did not include all expected areas of risk.	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	Standard Operating Procedures (SOPs) did not define that the reason, method and date of disposal must be documented.	**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 practice:

Number	Standard	Advice
1.	C1(a)	The ESBTB 'SOP for NOK post-mortem' procedure states that the biobank manager will take the next of kin through the correct ranking of the person who can provide consent for donation of a brain or tissue into the biobank. It refers to the HTA Codes of Practice, but does not include information on or from specific Code/s or list the hierarchy of qualifying relationships. To strengthen the procedure, the DI should consider updating the SOP to reflect the correct terminology as well as providing a reference to the relevant Code/s of Practice.
2.	C1(a)	The MRC CNMD Biobank receives samples with associated specimen forms. The forms each contain two tick boxes - one for 'consent for storage' and one for 'consent for research'. The consent for storage is where a donor has consented for the material to be stored for diagnosis. Although the consent form is always checked, the DI should consider whether the distinction between these two boxes is clear enough so that the clinical team understand how to avoid making potential errors.
3.	GQ2(a)	Audits demonstrate compliance with our standards and provide assurances that esblishments are meeting the requirements of their own systems and procedures. The DI should consider widening the scope of audits to include observational audits of staff undertaking processes.

Background

This was the second inspection of the establishment; the most recent previous inspection took place in August 2014.

Since the previous inspection, there has been an addition of two more satellite sites; the UK Dementia Research Institute at UCL and the MRC Prion Unit at UCL. At the time of the inspection, neither of these were storing relevant material under the governance of the HTA licence and were not inspected.

There are three research tissue banks storing relevant material under the licence - the ESBTB and the MRC CNMD Biobank are located at the hub site and the Queen Square Brain Bank for Neurological Disorders is located at the satellite site, UCL Queen Square Institute of Neurology.

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

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

Review of governance documentation

Key documents were reviewed, including, policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records.

Visual inspection

The hub and satellite site were visited as part of the inspection. A review of the licensed areas was undertaken, including areas where relevant material is received, processed and stored.

Audit of records

MRC CNMD Biobank

Traceability audits of three muscle biopsy samples were carried out (including from records to storage and storage to records). The consent forms for all samples were checked. There were no discrepancies.

ESBTB

A traceability audit of brain tissue donated following a coroner's post-mortem examination was carried out. A hospital post-mortem consent form was completed with evidence of brain donation for research. At the time of the audit, there were some discrepancies between the number of blocks and slides numbers associated with this donation when counted, possibly due to the large numbers. This was clarified after the site visit and it was confirmed that the number of blocks and slides in storage accurately reflected the traceability system. There were no further discrepancies.

Queen Square Brain Bank for Neurological Disorders

A traceability audit of a snap frozen brain tissue sample was carried out. As some of this tissue had been released for use in research, the associated Material Transfer Agreement (MTA) and record relating to the release of this tissue was reviewed. A review of the fixed half of the brain was also undertaken, with 57 blocks created from this material. These were in storage. A review of the consent form was also undertaken. No discrepancies were identified.

Meetings with establishment staff

Meetings with DI and research tissue bank staff carrying out licensable activities under the licence at both hub and satellite sites took place.

Report sent to DI for factual accuracy: 23 August 2023

Report returned from DI: 5 September 2023

Final report issued: 7 September 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 26 January 2024

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.