Inspection report on compliance with HTA licensing standards
Inspection date: **11 April 2023**

UKRI MRC London Institute of Medical Sciences

HTA licensing number 12240

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
UKRI MRC London Institute of Medical Sciences	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.

The UKRI MRC London Institute of Medical Sciences ('the establishment') was found to have met most of the HTA's standards; however, six minor shortfalls were identified against Governance and quality systems and traceability standards, in relation to standard operating procedures (SOPs), meetings, audits, risk assessments and the licensing status of material.

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 assessment.

Compliance with HTA standards

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment works are governed by documented policies and procedures as part of the overall governance process		
GQ1(a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	SOPs had not been reviewed in line with the defined review cycle period of two years.	**Minor**

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment works are governed by documented policies and procedures as part of the overall governance process		
GQ1(a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	There were no SOPs covering sample collection, sample receipt, sample labelling and cleaning / decontamination.	**Minor**

Standard	Inspection findings	Shortfall
GQ1 All aspects of the establishment works are governed by documented policies and procedures as part of the overall governance process		
GQ1(d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff	There were no regular governance meetings where matters relating to the HTA activities are discussed.	**Minor**

Standard	Inspection findings	Shortfall
GQ2 There is a documented system of audit		
GQ2(a) There is a documented schedule of audits covering licensable activities	An audit took place in 2022 but there was no documented schedule of audits.	**Minor**

Standard	Inspection findings	Shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
GQ6(a) Risk assessments are reviewed regularly	Risk assessments were not reviewed regularly.	**Minor**

Standard	Inspection findings	Shortfall
T1A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
T1(c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	The DI relies on completed self-assessments from research groups to maintain oversight of human tissue research across the establishment. At the time of the inspection, the DI had an incomplete record of self-assessment returns and therefore did not have complete assurance on the traceability and licensing status of all material.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	At the time of the inspection, some SOPs had review dates that had errors. The DI is advised to review all SOPs to ensure that typographical errors in review dates are corrected.
2.	GQ1(d)	The DI is advised to review membership of committees or meetings when considering the shortfall against GQ1(d) to ensure that group leads are also present where possible. This will help to ensure that all staff working with human tissue are aware issues that are relevant to them.
3.	GQ1(d)	The DI should consider covering audits, risk assessments and adverse events in meeting agendas to help ensure that matters relating to HTA-licensed activities are discussed and recorded.
4.	GQ6(a)	At the time of the inspection, there was a non-quantified and narrative approach to risk assessments, which did not provide actionable information on the adjusted risk after control measures were taken into account. The DI is advised to consider using a risk matrix approach for risk assessments so that risks can be scored and managed more effectively.
5.	GQ6(a)	The DI is advised to consider carrying out a risk assessment for storage capacity as this may be limited in some areas.

Background

The establishment is responsible for funding and co-ordinating medical research in the UK. The vast majority of storage is exempted from HTA licensing by virtue of qualifying research ethics committee approvals. Tissue may only be stored under the governance of the HTA licence after the research ethics approvals expire. The establishment was issued with their licence in 2017. This was the establishment's third HTA inspection. The establishment moved into a new building on the same premises in 2022 and had been involved in the relocation of tissue samples to the new building.

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

Of the 47 HTA standards, 46 were assessed (standards published 3 April 2017). Standards PFE2(b) was not applicable as the establishment does not work with material from deceased donors.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff competency records and records relating to traceability.

Visual inspection

A virtual tour of the storage area was undertaken as part of the virtual regulatory assessment.

Audit of records

There was no audit of records undertaken by the inspection team during the assessment. The establishment had not undertaken any regular audits and only one audit report was available for review.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI, Lead Research Nurse, Post- Doctoral Research Fellow involved in working with human tissue for research, the Head of Operations, the Deputy Head of Operations and the Corporate Licence Holder contact (CLHc).

Report sent to DI for factual accuracy: 5 May 2023

Report returned from DI: 5 May 2023 (with comments)

Final report issued: 5 June 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: 24 October 2023

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.