Inspection report on compliance with HTA licensing standards
Inspection dates: **5 August (remote) and 6 August (site visit) 2024**

University of Cambridge - Downing site
HTA licensing number 12196
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
University of Cambridge - Downing site (Hub)	Licensed	Not licensed
University of Cambridge- Old Addenbrooke's Site (satellite)	Licensed	Not licensed
University of Cambridge- West Cambridge Site (satellite)	Licensed	Not licensed
University of Cambridge- New Museums Site (satellite)	Licensed	Not licensed

MRC Epidemiology Sample Facility (satellite)	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 University of Cambridge - Downing site ('the establishment') was found to have met the majority of the HTA's standards, two minor shortfalls were identified against Governance and quality system standards relating to incident reporting and 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.

Compliance with HTA standards

Minor shortfalls

Standard	Inspection findings	Level of shortfall
GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use the incident reporting systems	There was no documented procedure that included the steps that must be followed by staff to identify and report an adverse event.	**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.	Some groups' risk assessments did not contain adequate information on how each risk is mitigated.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Each research group has standard operating procedures (SOPs) in place which cover activities associated with human tissue receipt, storage, use and disposal. While some groups' SOPs included processes that could be followed step-by-step, others had SOPs that lacked this level of detail. The DI should consider a full review of each group's SOPs to ensure that they can be followed in a stepwise fashion.
2.	GQ1(a)	The Gurdon Institute stores human tissue slides from living donors which have previously been used in teaching in schools under a material transfer agreement. These are currently not being used; however, the DI is advised to develop documented procedures to cover how the tissue slides are to be handled, stored and used should this activity restart.
3.	GQ1(b)	It was noted that some groups did not have version numbers on SOPs while others did. The DI should ensure that there is a consistent approach to document control across all groups.

4.	GQ2(b)	Research groups perform regular audits, which are recorded on forms developed by each group. To support the consistent recording of audit findings, the DI should consider unifying the process for recording audits; for example, by using standardised templates.
5.	GQ6(a)	The establishment carries out regular maintenance of the fridges and freezers that store human tissue and will replace these if there is a breakdown. As there is no service contract in place, the DI is advised to factor this into the assessment of risks relating to the storage of human tissue.
6.	PFE1(b)	The Pathology group stores 'wet' tissues in a fridge in the Pathology laboratory. Although the department is secure, with swipe card access, the Pathology fridge is unlocked. The DI should consider assessing if there are any risks to the tissue stored in this way.

Background

The University of Cambridge - Downing site ('the establishment') operates under a hub-and-satellite licensing arrangement, with four satellite sites storing human tissue for use in research. The establishment works with another HTA-licensed establishment that has responsibility for obtaining consent and collecting tissue from patients as part of a research tissue bank. The human tissue is then stored and used by departments across the licensed establishment. The vast majority of human tissue is stored under the governance of a recognised ethical approval; however, there were also collections stored under the governance of the HTA licence, including existing holdings (samples obtained prior to 1st September 2006).

The following groups were included as part of the inspection:

- Department of Pathology
- Physiology, Development and Neuroscience
- Gurdon Institute
- MRC Toxicology Unit
- Department of Physics
- MRC Epidemiology Unit

The New Museums Site (satellite site) was not visited as part of this inspection due to the low risk and limited activity taking place.

This report describes the second inspection of the establishment. The previous inspection took place in 2018.

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 standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, sample tracking system, temperature monitoring data and incidents.

Visual inspection

A visual inspection of the hub and three satellite premises was carried out.

Audit of records

Department of Pathology

An audit from electronic records to storage locations of a tissue section, ‘wet’ tissue, five formalin-fixed paraffin embedded (FFPE) tissue blocks and 11 slides was carried out. All material was fully traceable and no discrepancies were identified.

Physiology, Development and Neuroscience

An audit from electronic records to storage locations of fresh and frozen tissue samples was carried out. All material was fully traceable and no discrepancies were identified.

An audit from the storage location to the electronic records of an existing holding tissue sample was carried out. The sample was fully traceable and no discrepancies were identified.

Gurdon Institute

An audit from electronic records to storage locations of three frozen tissue samples was carried out. All material was fully traceable and no discrepancies were identified.

An audit of one frozen sample from the storage location to the electronic records was carried out. The sample was fully traceable and no discrepancies were identified.

MRC Toxicology Unit

An audit trail from electronic records to storage locations of three tissue blocks was carried out. All material was fully traceable and no discrepancies were identified.

A further audit of eight tissue slides was carried out. These were identified in storage and linked to the electronic records. All material was fully traceable and no discrepancies were identified.

Department of Physics

An audit from electronic records to storage locations of two frozen samples was carried out. At the time of the inspection, the vials could not be found in their allocated positions in the specified box. After the inspection, evidence was provided to confirm that the vials were present in the box but in different (unexpected) positions which had not been recorded on the tracker. Following the identification of this discrepancy, the establishment confirmed that the electronic records had been updated to indicate the new location of the vials.

A further audit of two tissue slides from storage locations to electronic records was carried out. All material was fully traceable and no discrepancies were identified.

MRC Epidemiology Unit

An audit from electronic records to tissue storage locations of two frozen tissue samples was carried out. All material was fully traceable and no discrepancies were identified. A further audit of two frozen tissue samples from the storage locations to the electronic records was carried out. All material was full traceable and no discrepancies were identified.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Persons Designated (PDs) for each department, Director of Health and Safety and Regulatory Affairs and Interim Head of Safety.

Report sent to DI for factual accuracy: 3 September 2024

Report returned from DI: 16 September 2024 (with comments)

Final report issued: 26 September 2024

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: 12 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.