Inspection report on compliance with HTA licensing standards
Inspection date: **1 July 2024**

Ear Institute
HTA licensing number 12161

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
Ear Institute	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 Ear Institute ('the establishment') was found to have met the majority of the HTA's standards, five minor shortfalls were identified – these were against Governance and quality systems (GQ) and Traceability (T) standards.

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
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	Temporal bone blocks and slides are used by Masters degree students carrying out research projects once a year. The procedures in place do not reflect how the collection is used to support this work, including - but not limited to - how tissue is identified, removed for use, stored and then returned.	**Minor**

GQ2 There is a documented system of audit		
a)There is a documented schedule of audits covering licensable activities	The establishment has not performed any audits in relation to the temporal bone collection or the research samples comprising stapes bones and blood samples.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	The paper records pertaining to the research samples, including consent forms and traceability records, are not backed up electronically.	**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.	The control measures in the risk assessments for the temporal bone tissue blocks and slides collection do not contain sufficient detail, meaning that risk assessments do not document how risks are mitigated.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and its associated products where relevant, is maintained.	An inventory of the temporal bone collection records the type of material stored, along with specimen details and case information but it does not record the number of blocks and slides stored for each case.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ3(b)	Each year, the Person Designated (PD) for the temporal bone collection will oversee two students completing research projects. The students are given a temporal bone laboratory induction before they can start working with tissue slides. The DI should consider developing a code of conduct, or similar set of expectations, which each student is required to sign-up to before they commence their work. This may help to strengthen the DI's assurance that the students have understood their responsibilities before accessing the laboratory.
2.	GQ5(a)	The adverse events standard operating procedure (SOP) lists the types of incidents that may occur. To improve understanding and strengthen compliance with the procedure, the DI should consider adding examples of adverse events relevant to the temporal bone laboratory.
3.	GQ6(a)	The contingency freezer is switched off until required The DI should formally assess the risks of this approach in the event of sudden freezer failure.
4.	T2(b)	Although the establishment has not disposed of any relevant material, the DI should consider amending the sample databases so that there is a section where the disposal reason, method and date can be recorded.

Background

The Ear Institute (the establishment) stores blood and tissue blocks and slides under the governance of the HTA licence. Since 2023, the establishment no longer hosts the annual rhinoplasty course which involved the import of fresh frozen cadaveric heads.

The establishment stores a collection of blocks and slides (existing holdings) which are used annually by a few Masters degree students undertaking research projects. At the time of the inspection, the establishment was also storing stapes bones (as frozen tissue) and blood samples that had been collected under the governance of an NHS Research Ethics Committee (REC) approval. As the ethics approval had lapsed, these samples were being stored under the governance of the HTA licence. This report describes the third HTA inspection of the establishment.

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, 40 standards were assessed (standards published 3 April 2017). HTA standards, C1(b),(d),(e),(f) and C2(a),(b),(c) were not applicable as the establishment is not directly involved in seeking consent.

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 premises where licensable activity takes place was carried out.

Audit of records

Research samples

An traceability audit was carried out for a recorded frozen tissue sample and a blood sample identified from the sample database and tracked to the physical storage locations. At the time of the audit, the samples could not be found in their expected respective storage locations. It was confirmed from documents that the tissue sample was never collected in theatre as expected and the blood sample was processed and no longer stored.

A further audit was carried out for a frozen tissue sample and blood sample identified from the sample database and tracked to the physical locations. These samples were found in storage and no discrepancies were noted.

A reverse audit of two frozen tissue samples from their storage locations to the sample database was carried out. The consent records linked to these samples were also reviewed; no discrepancies were noted.

Temporal bone blocks and slides.

An audit of blocks and slides (originating from the left and right ear) from their physical storage locations to the sample database was carried out.

A reverse audit was carried out of blocks and slides (originating from the right temporal bone and middle ear) was carried out.

In both audits, the sample database linked with the blocks and slides held. No discrepancies were found.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Persons Designated (PDs) and Institute Manager.

Report sent to DI for factual accuracy: 24 July 2024

Report returned from DI: 16 August 2024 (no comments)

Final report issued: 19 August 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: 7 July 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.