Inspection report on compliance with HTA licensing standards
Inspection date: **22 July 2024**

Royal Devon and Exeter Hospital
HTA licensing number 12276

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
Royal Devon and Exeter Hospital	Licensed	Not licensed
Heavitree Hospital	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 Royal Devon and Exeter Hospital ('the establishment') was found to have met the majority of the HTA's standards, two minor shortfalls were identified against Governance and quality system and Traceability standards, relating to records management and disposal.

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
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 consent forms stored from the Exeter 10,000 study and Peninsula Research Bank were in paper copy and not backed up. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) Disposal is carried out in accordance with the HTA's Codes of practice.	The establishment's disposal procedure did not state the requirement that the date of disposal must be recorded. *"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 Royal Devon and Exeter Tissue Bank collects and stores human tissue for research studies that are approved by the establishment's steering committee. The Experimental Medicine Research Officer is responsible for obtaining consent and collecting and processing the human tissue samples. To strengthen resilience in these activities, the DI should consider developing procedural documents to cover key processes such as how participants are recruited, their consent obtained and how samples are collected.
2.	GQ2(a)	The DI had recently initiated a new system of audits following a lack of audits since 2022. Each group storing relevant material under the licence is now required to complete an 'annual returns audit form' which the DI reviews to schedule an audit visit. The DI should consider extending the scope of auditing to include vertical and horizontal audits to strengthen assurances further.

3.	GQ2(a)	All tissue samples stored for research projects that are coming to the end of their project specific ethics approval will be transferred under the governance of the HTA licence. A review of the studies to see whether they meet the requirements of the HTA standards is undertaken once ethical approval ceases. To strengthen the governance around this process, the DI is advised to introduce a system which seeks to identify whether the HTA standards are being met prior to the transfer of tissue under the licence. This will help to ensure that any compliance issues are identified earlier.
4.	GQ3(a)	The establishment refers staff to HTA training which has been developed by another HTA-licensed establishment. Although this includes information on meeting HTA standards, it is tailored to the originating establishment. The DI is advised to develop internal HTA training resources.
5.	GQ5(a)	To strengthen incident reporting, the DI is advised to consider adding examples of reportable incidents to the adverse event procedure.
6.	T1(c)	The date a sample is released from the Exeter 10,000 and Peninsula Research Tissue Bank is recorded on an MTA. As this information forms part of the sample traceability record, the DI should consider recording the date samples are released on the sample database. This will ensure that the date samples are released is recorded centrally and can be accessed readily.

Background

Royal Devon and Exeter Hospital (the establishment) stores human tissue under a hub and satellite licensing arrangement. The establishment collects and stores relevant material from living donors under the governance of two research tissue banks; these are the Royal Devon and Exeter Tissue Bank and the Exeter 10,000 and Peninsula Research Tissue Bank. Consent is obtained by trained staff. The Royal Devon and Exeter Tissue Bank has ethical approval to collect for specific research studies which must be approved by a steering committee. This report describes the second 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, 46 standards were assessed (standards published 3 April 2017). PFE2(b) is not applicable as the establishment does not store material from the deceased.

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

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards. A presentation of the areas where human tissue was stored at the hub and satellite sites was shared during the assessment.

Audit of records

No traceability audit was carried out; however, a review of recently conducted audits was undertaken as part of the assessment.

Meetings with establishment staff

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

Report sent to DI for factual accuracy: 19 August 2024

Report returned from DI: 11 September 2024 (with comments)

Final report issued: 25 September 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.