Inspection report on compliance with HTA licensing standards
Inspection date: **24 April 2024**

Cerevance Limited
HTA licensing number 12649

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
Cerevance Limited	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 Cerevance Limited ('the establishment') was found to have met the majority of the HTA's standards, two minor shortfalls were identified – one against a Governance and quality system (GQ) standard and one against a standard for Premises, facilities and equipment (PFE).

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.	Although the establishment had a documented procedure in place (CER-SOP-HT-054) which includes processes relevant to receipt, storage, transport and disposal of human tissue, some sections of the procedure lacked sufficient detail to enable a member of staff to follow a process in a stepwise fashion. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures	The establishment did not have a cleaning and decontamination procedure in place. *"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)	Although there had not been any cases where consent had been withdrawn, the DI should consider making the current procedure clearer on how the sample tracking system should be updated to reflect that consent has been withdrawn. This will help to minimise any risk that a sample may be used after the establishment has been informed that consent has been withdrawn.
2.	GQ1(a)	SOPs are subject to regular review; however, to strengthen this process, the DI should consider including reviews by staff involved in licensable activities.
3.	GQ2(a)	To gain wider assurances, the DI is advised to consider extending the range of audits to include coverage of processes and procedures, for example staff undertaking a specific task.

4.	GQ2(b)	Discrepancies identified during traceability audits are documented during the audit and corrected immediately without the requirement for a corrective action plan. To ensure that actions other than discrepancies are adequately followed up, the DI should ensure that where necessary audit actions and staff responsible for their follow up are documented.
5.	GQ5(a)	The DI should consider adding incident types to the incident reporting procedure, examples of which can be found in the HTA's Research Licensing Standards and Guidance document. This will help to remind staff about the types of incidents which will need to be reported and investigated internally.
6.	GQ6(a)	Although the establishment had sufficient control measures to prevent use of samples following withdrawal of consent, the risk assessment itself could reflect these more clearly. The DI is advised to review this section and provide further details.
7.	T1(c)	New staff are given training in using the sample tracking system by the Person Designated (PD) as part of the induction process. The DI is advised to develop instructions on how to record sample traceability using the system to ensure that a consistent approach is taken to entering data to track a sample from receipt to storage, use and disposal.
8.	PFE2(c)	The DI should consider adopting regular trend analysis of critical storage temperatures. This may help with preventative maintenance of equipment and detect any malfunctioning equipment ahead of a possible failure.

Background

Cerevance Limited (the establishment) is a pharmaceutical company which specialises in diseases of the central nervous system. The establishment stores and uses frozen or fixed tissue for research, from brain banks within and outside of the United Kingdom (UK). No consent is sought at the establishment. Occasionally the establishment transfers fixed tissue for histological analysis to another HTA-licensed establishment.

This was the first inspection of the establishment since its licence application assessment in April 2016.

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

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards. Photographs of storage areas were reviewed during the assessment.

Audit of records

No traceability audit was carried out; however, a review of recently conducted traceability 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, Person Designated (PD) and a staff member from the Information Technology team.

Report sent to DI for factual accuracy: 20 May 2024

Report returned from DI: 31 May 2024

Final report issued: 19 June 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.