

Inspection report on compliance with HTA licensing standards  
Inspection date: **7 March 2023**



**The Walton Centre**  
HTA licensing number 12030

Licensed under the Human Tissue Act 2004

**Licensed activities**

<b>Area</b>	<b>Storage of relevant material which has come from a human body for use for a scheduled purpose</b>	<b>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</b>
The Walton Centre	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 HTA found that The Walton Centre (the 'establishment') had met all of the HTA's licensing standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

## Advice

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

Number	Standard	Advice
1.	C1(a)	The HTA was assured that consent is obtained from the most appropriate person under the Human Tissue Act 2004 for donations to the Liverpool Neuroscience Biobank at The Walton Centre; however, to provide greater clarity, the DI is advised to review the consent documentation and consider replacing references to 'Next of Kin'.
2.	GQ1(a)	Documents, including SOPs, are only redistributed to staff if changes are made during the review process. The DI may wish to consider redistributing regardless of whether there have been changes made to ensure that staff are fully trained and up to date on policies and procedures relevant to their work.
3.	PFE1(a)	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the DI is advised to consider including signage on the freezers, highlighting that human samples are contained within.

## Background

The Walton Centre has been licensed by the HTA since June 2007. This was the second inspection of the establishment; the most recent inspection took place in December 2013.

Since the previous inspection, there have been some significant changes to the licence arrangements, including changes of DI in June 2016 and December 2017.

## Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

*Standards assessed against during inspection*

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

*Review of governance documentation*

Policies and procedural documents relating to all licensed activities, including standard operating procedures were reviewed. Documents detailing staff training, internal audits, risk assessments and incidents were reviewed, as well as consent-seeking procedures and information used to support the seeking of consent from donors to Liverpool Neuroscience Biobank at The Walton Centre.

*Visual inspection*

No visual inspection was undertaken as part of this inspection; however a meeting with relevant staff members took place to discuss the Premises, facilities and equipment (PFE) standards.

*Audit of records*

No traceability audits were carried out; however, the establishment's internal audits were reviewed. These included clinical, vertical, horizontal, traceability and examination/witness audits.

*Meetings with establishment staff*

The assessment included discussions with the Biobank Manager, a Chief Biomedical Scientist, the Quality Manager, Clinical Scientists, the Medical Director (who holds the position of Corporate Licence Holder contact, CLHc) and a Neuropathologist (who holds the position of DI).

**Report sent to DI for factual accuracy: 9 March 2023**

**Report returned from DI: No factual accuracy or request for redaction comments were made by the DI**

**Final report issued: 17 March 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.