Inspection report on compliance with HTA licensing standards
Inspection date: **17 November 2021**

Manchester University NHS Foundation Trust - Central Hospitals

HTA licensing number 12552

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
Hub site **Manchester University NHS Foundation Trust - Central Hospitals**	Licensed	Not licensed
Satellite site **Wythenshawe 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.

Manchester University NHS Foundation Trust - Central Hospitals ('the establishment') was found to have met all HTA standards.

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C1(d)	Two of the establishment's Research Tissue Banks (RTBs) export tissue to researchers in the USA. The patient information sheets and consent forms do not mention export. The DI is advised to modify this documentation to ensure that fully informed consent has been sought for this activity.
2.	GQ2(b)	Audit findings and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording audit findings, discussions about the audit, who is responsible for follow-up actions and the timeframes for completing these.
3.	GQ5(b)	Adverse events and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording adverse event findings, discussions about the adverse event, root cause analysis and resulting corrective and preventative actions.

4.	PFE2(c)	Two storage rooms contain formalin-fixed tissue and formalin-fixed paraffin wax-embedded blocks and sections at ambient temperature; these rooms are not temperature monitored. Excessive or prolonged raised temperatures in these rooms may lead to biomarker degradation. The DI is advised to risk assess these current arrangements and consider the effects that storage temperature deviations could have on the quality of samples stored.

Background

Manchester University NHS Foundation Trust - Central Hospitals contains eight NHS REC-approved, HTA-licensed RTBs. Seven of these are at the hub and one at the satellite. The establishment also stores relevant material from living and deceased donors for 16 research groups. At the time of the inspection, relevant material from 47 collections was being stored. Approximately 60% of these have current UK Ethics Committee Authority (UKECA) approval or NHS Research Ethics Committee (REC) project-specific approval, and the storage of these samples is exempted from HTA licensing. The remaining studies fall under the licence.

The establishment has been licensed by the HTA under this licence since September 2009, although it was licensed under two separate and different licences before that date. This was the second inspection of the establishment; the last one took place in January 2010. The satellite was separately inspected under another licence, in August 2016.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was registered with the HTA in November 2018 and nine Persons Designated (PDs) have been added to the licence. The satellite was added to the licence in December 2018.

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 assessment (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed, temperature monitoring records, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, meeting minutes, the management of complaints, staff training records, and risk assessments.

Five of the establishment's internal audits were reviewed. Advice is provided about the management of audits (see *Advice*, item 2).

Four reported adverse events were reviewed. Advice is provided about the management of adverse events (see *Advice*, item 3).

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

As there was no visual inspection undertaken, no formal audit of records was carried out.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, representative of the CLHc, six PDs (including one based at the satellite), an RTB manager, a Senior Scientist and a Biomedical Scientist. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 14 December 2021

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

Final report issued: 19 January 2022

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.