Inspection report on compliance with HTA licensing standards
Inspection date: **5 July 2022**

St James's University Hospital
HTA licensing number 12352

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
St James's University Hospital	Licensed	Not licensed
University of Leeds (Satellite)	Licensed	Not licensed
Chapel Allerton Hospital (Satellite)	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.

St James's University Hospital ('the establishment') was found to have met most of the HTA's standards; however, one minor shortfall was identified against GQ2(a) in relation to the approach to audits.

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 shortfall identified during the assessment.

Compliance with HTA standards

Standard	Inspection Findings	Shortfall
GQ2 There is a documented system of audit		
GQ2(a) There is a documented schedule of audits covering licensable activities	Each research group is responsible for inspecting their own areas for HTA compliance. There is no consistent approach to the way in which audits are being scheduled or undertaken, with some groups focussing only on traceability and other groups undertaking audits against a wider range of HTA standards.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The Neuro Research Tissue Bank stores material from the living and deceased. Consideration has been given as to whether patients admitted to the hospital in an emergency can donate research samples, including those who may temporarily be unable to make a decision. In addition to the guidance provided in HTA's Code A: Guiding Principles and the Fundamental Principle of Consent, the DI is advised to have due regard to the Mental Capacity Act 2005 and associated guidance, including the Code of Practice.

2.	C1(c)	The Biological Sciences group imports relevant material from outside of the UK. A specific form is filled in by staff before relevant material can be imported for storage and use in research. The form contains a section where confirmation that the consent status of the material to be supplied has been checked; however, it does not make it clear whether this is for research within the scope of the Human Tissue Act 2004 (the 'Act'). Although this is imported material, and the consent provisions of the Act do not apply, the DI is advised to revise the form to provided evidenced assurance that imported material has been sourced with appropriate consent.
3.	C2(a)	Consent training is managed by each research group. The DI is in the process of developing a centralised consent training package which all researchers can access. The DI should consider reviewing the content of training that groups currently deliver to identify any good practice or gaps that could be covered in the centralised consent training package.
4.	C2(c)	All research groups involved in seeking consent are appropriately trained and there is an audit of consent undertaken each quarter by the HTA Manager. The DI may wish to adopt an approach where newly trained staff are observed seeking consent to ensure that staff are able to demonstrate key competencies. This will help to strengthen the approach to consent training and will help to identify any learning gaps.
5.	GQ1(a)	The establishment encourages the adoption of overarching SOPs which cover licensed activities such as receipt, storage, processing, and disposal of relevant material. Individual research groups use these overarching documents to guide the development of SOPs for their respective areas. It was identified during the inspection that the approach to writing SOPs was markedly different across all research groups, with some documents more comprehensive compared to others. In order to give greater assurance to the DI regarding consistency in approach, the DI is advised to consider how current ways of working could be harmonised; for example, the management of samples stored under the licence and those for Health Research Authority (HRA)-approved research.

6.	GQ1(d)	The DI may wish to consider adding regular agenda items that seek to improve consistency and alignment across research groups; for example, in the approaches to auditing or developing SOPs.
7.	GQ2(a)	At present, research groups audit their own research areas. The DI may wish to explore whether research groups could audit one another's research areas, which may offer a degree of independence to the audit process and lead to shared learning.
8.	GQ2(b)	The DI is advised to consider developing an audit template to improve the consistency in approach to undertaking audits.
9.	PFE2(c)	Critical storage conditions are appropriately monitored and alarmed, with notifications sent out when there is a temperature excursion. The alarms are not tested at present, as the establishment relies upon the notifications from temperature excursions that occur routinely to provide assurances that systems are working as expected. To strengthen this approach, the DI may wish to consider documenting this formally to ensure the call out process is working as expected and may wish to consider regular alarm system tests.

Background

This was the third routine inspection of the establishment. The establishment was previously inspected in 2013 and 2017. The establishment has several Research Tissue Banks (RTBs), tissue collections and projects with HRA approval across the hub and satellite sites. The groups are listed below:

- Biological samples
- Arthritis
- Promote study (project specific HRA approval)
- Root Study (project-specific HRA approval)

- Dental and Skeletal RTB
- Neuro RTB
- Leeds NIHR RTB
- PNH RTB
- VII RTB
- Leeds Multi RTB

Samples from living and deceased donors are stored in HRA-approved RTBs which collect, store and release tissue for research purposes. Samples from deceased donors are also imported from the USA, and stored and used in research by one of the research groups.

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

All 47 standards were assessed (standards published 3 April 2017).

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, study audits including an audit against HTA standards, meeting minutes, staff training records, traceability records 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.

Audit of records

No traceability audits were carried out; however, a review of the establishment's audits was undertaken as part of the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff and included the DI, HTA Manager, PDs and representatives from each research group involved with licensed activities.

Report sent to DI for factual accuracy: **21 July 2022**

Report returned from DI: 3 August 2022 (with comments)

Final report issued: 5 September 2022

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: 8 February 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.