Inspection report on compliance with HTA licensing standards
Inspection date: **25 January 2023**

Guy's Hospital

HTA licensing number 12121

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 Guy's Hospital	Licensed	Not licensed
Satellite St Thomas' 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 the HTA found that Guy's Hospital ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for Governance and quality systems in relation to internal 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 inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Whilst there is a documented schedule of audits, during recent years this has not been followed. Audits have been infrequent and limited in scope. Not all collections that are stored under the licence are included in the audit schedule.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment's consent policy references the HTA's former Codes of Practice and licensing standards. The DI is advised to update this reference to the current documents which were published 3 April 2017.
2.	C1(b)	Clinical staff involved in consent seeking for the Biobank have access to the establishment's consent policies and SOP; however, there is no system to record that they have read and understood them. The DI is advised to implement a procedure that confirms that these staff members have read and acknowledged the current versions of documents.
3.	C2(a)	Although staff are required to be trained in seeking and obtaining consent, this is not detailed within the establishment's overarching consent policy. The DI is, therefore, advised to document the requirements.
4.	GQ1(a)	Staff have access to a shared system where all the establishment's documents are held. The DI may wish to include a link to the HTA's Codes of Practice A (Consent) and E (Research) in order for staff to maintain awareness of current standards, legislation and requirements.
5.	N/A	There are no Persons Designated (PDs) named on the licence. The DI is advised to consider adding PDs who can assist them in ensuring compliance with HTA standards.

Background

Guy's Hospital has been licensed by the HTA since September 2007. This was the second inspection of the establishment; the most recent inspection took place in November 2013.

Since the previous inspection, there have been some significant changes to the licence arrangements, including the addition of a satellite premises at St Thomas' Hospital in September 2014. Although licensed, the DI confirmed that currently there is no licensable activity taking place at the site.

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 and risk assessments, were assessed. Documents detailing staff training, internal audits and incidents were reviewed, as well as consent-seeking procedures and information used to support the seeking of consent from donors to the King's Health Partners (KHP) Cancer Biobank.

Visual inspection

No visual inspection was undertaken as part of this inspection; however, a video tour of the four main storage areas was provided virtually. This included the main freezer room, back-up freezer room, archive storage room and back-up archive storage room. Furthermore a meeting with relevant staff members took place to discuss the PFE standards.

Audit of records

No traceability audits were carried out; however, the establishment's internal audits were reviewed. These included 2020/2021 audits of staff training records and traceability. More recently, in January 2023, the establishment overhauled their auditing procedures to include full traceability audits from consent documentation, to database records, to sample location as well as auditing against the HTA's standards. The recent audit reports carried out by the Quality Manager were reviewed.

Meetings with establishment staff
The assessment included discussions with the Biobank Manager (who holds the position of DI), the Director of Research and Development (who holds the position of Corporate Licence Holder contact, CLHc), the Consent Co-ordinator, the Clinical Trials Manager, the Quality Manager and Biobank technicians and researchers.

Report sent to DI for factual accuracy: 02 February 2023

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

Final report issued: 03 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.