Inspection report on compliance with HTA licensing standards
Inspection date(s): **17 July (remote) and 23-25 July 2024 (site visit)**

Royal Brompton Hospital

HTA licensing number 12388

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 Royal Brompton Hospital	Licensed	Licensed
Satellite Harefield Hospital	Licensed	Licensed
Satellite Royal Brompton Campus - Emmanuel Kaye Building	Licensed	Not licensed
Satellite Royal Brompton Campus - Guy Scadding Building	Licensed	Not licensed
Satellite South Kensington Campus - Sir Alexander Fleming Building	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 Royal Brompton Hospital (‘the establishment’) had met the majority of the HTA’s standards, two minor shortfalls were found against standards for Governance and quality systems. These related to the carrying out of audits and the distribution of risk assessments.

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.

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	Audits had not been carried out in line with the establishment's SOP meaning that some collections had not been audited for a number of years.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Staff can access risk assessments and are made aware of risks during training	Due to a change in the governance systems, overarching risk assessments that cover practices and processes relating to licensed activities had not been distributed to relevant staff for a number of years.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The footer within the 'Guidance document for obtaining informed consent for research participation- RO/G/003' has not been updated in line with the most recent document review. The DI is advised to update the reference for clarity. Furthermore, the link to the HTA's Code of Practice on Consent is broken.
2.	GQ1(d)	There are regular meetings with staff at the establishment who are engaged in licensed activities; however, there is a delay in the typing up and distribution of meeting minutes. The DI is advised to finalise and circulate the outputs from the meetings more quickly so that actions are clearly documented and followed up. This should also help to ensure that all relevant staff are made aware of important information relating to licensed activities in a timely manner.

3.	PFE1(b)	One of the collections audited at the Harefield Hospital satellite premises had the research freezer within a laboratory corridor. Although there is controlled access to the overall building and corridor, it is accessed by a number of other groups. The human tissue samples are from a static collection and not regularly accessed. The DI is advised to consider whether any additional signage or security measures may add a higher level of protection to the samples.

Background

Royal Brompton Hospital has been licensed by the HTA since October 2007. This was the third inspection of the establishment; the most recent inspection was the licence application assessment that took place in August 2017.

Since the previous inspection, there have been some significant changes to the licence arrangements including changes to the DI in April 2023 and June 2023, and a change of Corporate Licence Holder contact in January 2020.

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 for research projects.

Visual inspection

The Regulation Manager undertook a site visit inspection of Royal Brompton and three of the four satellites which included Harefield Hospital, Royal Brompton Campus - Guy Scadding Building and South Kensington Campus - Sir Alexander Fleming building. The visual inspection included the laboratory areas where samples are stored and the office areas where paper records are stored.

Audit of records

Traceability audits were carried out at each site which included five individual research collections and two research tissue banks held under the licence. The audit included 47 samples taken from 26 donors. Traceability details were cross-checked between the identification details on the sample vials, information on the electronic and paper records and the associated consent forms. All samples were fully traceable and no discrepancies were identified.

Meetings with establishment staff

The assessment included discussions with the Tissue Governance Manager, laboratory managers, scientists involved in the research, the biobank manager, biobank sample coordinators and a Consultant Physician, and Director of Research (who holds the position of DI).

Report sent to DI for factual accuracy: 6 August 2024

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

Final report issued: 16 August 2024

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 January 2025

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.