Inspection report on compliance with HTA licensing standards
Inspection dates: **7 December (remote assessment) and 8 December (site visit) 2022**

Royal Marsden Hospital

HTA licensing number 30000

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
Royal Marsden Hospital Hub (Chelsea)	Licensed	Not licensed
Royal Marsden Hospital Satellite (Sutton)	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.

Royal Marsden Hospital ('the establishment') was found to have the met all of HTA's 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.	GQ1(d)	The DI may wish to consider adding incidents, audits and risk assessments as formal agenda items to the Human Tissue Working Group meetings that take place quarterly. This may help to ensure that matters relating to these agenda items are brought to the meeting.
2.	GQ2(a)	Each tumour-specific bank is required to complete a self-assessment against the HTA's standards. The self-assessment is used by each research group to assess how they are meeting the standards and also by the DI to review areas for improvement. The DI may wish to consider how the benefits of these audits can be optimised as part of the wider audit programme, including the frequency of the self-assessment process and whether there could be auditing between groups to promote shared learning.
3.	GQ2(a)	The DI may wish to consider including audits where each tumour specific bank conducts audits of each other's storage areas. This will help to establish a degree of independence during the audit process as well as promote shared learning.
4.	GQ2(a)	The DI may wish to consider including audits which focus on processes, such as staff undertaking particular tasks relating to receipt, storage, use or disposal of human tissue. This may help to extend the scope of audits so that they cover a wider range of activities.

5.	GQ6(a)	Biobank staff are responsible for undertaking risk assessments for samples that have been collected through the tumour-specific banks and then subsequently stored in the Biobank. The DI may wish to strengthen the risk assessments by ensuring that key procedures and documents which are in place to reduce risks are clearly highlighted within the assessment.
6.	PFE2(c)	The DI may wish to consider including a regular schedule of alarm testing to check that the system is working as expected.
7.	PFE2(c)	The storage areas containing the -80°C freezers are air conditioned. The DI may wish to consider adding the room temperatures of the storage facilities at hub and satellite site to the monitoring system.
8.	N/A	Storage activities at the satellite site were found to be significantly greater than at the hub site, which is not in line with the normal expectations of the HTA's hub-satellite licensing model. This will be evaluated further.

Background

The establishment is a specialist cancer centre which holds a Biobank and associated tumour-specific banks across the hub (Chelsea) and satellite (Sutton) sites. The Biobank provides storage services to some of the tumour-specific banks, while other storage activities are managed locally by Persons Designated (PDs). The inspection focussed on the Biobank and three tumour-specific research tissue banks.

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

Of the 47 HTA standards, 46 were assessed (standards published 3 April 2017). Standard PFE2(b) was not applicable.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff competency records and records relating to traceability.

Visual inspection

A site visit inspection took place on 8 December 2022, during which the storage facilities at the hub and satellite sites were reviewed.

Audit of records

Traceability audits were undertaken during the site visit inspection.

Four samples were identified at the hub site and audited from their records to their freezer storage locations. Two samples were identified at the satellite site and audited from their records to their freezer storage locations. No discrepancies were identified.

Furthermore, one reverse audit from their freezer storage location to the record was undertaken at the satellite site. A record relating to a sample that was shipped out from the satellite site was also seen along with its material transfer agreement. No discrepancies were identified.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and PDs for three tumour specific banks.

Report sent to DI for factual accuracy: 9 January 2023

Report returned from DI: 12 January 2023 (with comments)

Final report issued: 18 January 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.