Inspection report on compliance with HTA licensing standards
Inspection date: **20 January 2023**

Institute of Cancer Research

HTA licensing number 12322

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
Institute of Cancer Research (Chelsea)	Licensed	Not licensed
Institute of Cancer Research (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.

Although the Institute of Cancer Research ('the establishment') was found to have the met most of the HTA's standards, two minor shortfalls were identified against standards for Governance and quality systems (risk assessments) and Traceability (register of donated material).

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
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
GQ6(a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The establishment was not able to provide evidence of any risk assessments relating to HTA-licensed activities at the time of the inspection. A draft risk assessment was received after conclusion of the inspection. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	Shortfall
T1 A Coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail.		
T1(b) A register of donated material, and the associated products where relevant, is maintained.	One of the research groups storing relevant material under the governance of the HTA licence were also storing tissue from deceased donors in its freezers following the conclusion of an ethically-approved research study that ran between 2015-2018. These samples had not been recorded in the establishment's traceability system.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment is the sponsor on a clinical trial involving multiple sites and are in receipt of samples collected from patients. The 'Sample Packing Slip' form confirms that consent to donation has been given, however does not explicitly state consent to research use. As the samples from this trial may be stored under the governance of the HTA licence in future, the DI is advised to consider amending the template to ensure that it is clear that consent for research use has been given.
2.	GQ1(a)	The DI is advised to consider adding the review cycle and revision history to local research group SOPs to ensure that this information is clear to the reader accessing the procedure.
3.	GQ1(d)	The DI is advised to consider adding incidents, audits and risk assessments as formal agenda items to the Human Tissue Working Group meetings that take place quarterly. This will help to ensure that any business relating to these agenda items are brought formally to the meeting.
4.	GQ2(a)	Each research group is required to complete a self-assessment against the HTA's standards. The self-assessment is used to assess how they are meeting the standards and also by the DI to review areas for improvement. The DI is advised to consider how this information is used as part of the wider audit programme and to agree the frequency of the self-assessment process.
5.	GQ2(a)	The DI may wish to consider including audits where one research group audits another group's storage area. This may help to establish a degree of independence during the audit process as well as promote shared learning.

6.	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 and/or disposal of human tissue. This will widen and may help to strengthen the scope of the audits.
7.	GQ6(a)	The DI is advised to strengthen risk assessments by ensuring that key procedures and documents which are in place to reduce risks are clearly highlighted within the assessment.
8.	PFE2(c)	The DI may wish to consider including a regular schedule of alarm testing to check that the system is working as expected.

Background

The establishment is a cancer specialist centre that works closely with the Royal Marsden Hospital and operates under a hub (Chelsea) and satellite (Sutton) licensing arrangement. The establishment and the Royal Marsden Hospital operate under the same governance, with staff working across both establishments. The establishment also uses relevant material from a Research Ethics approved Biobank which stores tissue samples under the governance of its HTA-licence at the Royal Marsden Hospital.

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 pre-recorded video of one of the HTA licensed storage areas was shared during the assessment which provided an overview of the security arrangements

Audit of records

Research groups undertake a forward and reverse audit of samples and associated records as part of a self-assessment process. Furthermore, a team is dedicated to auditing the traceability system data entries for samples on a yearly basis.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and PDs for three research groups.

Report sent to DI for factual accuracy: 17 February 2023

Report returned from DI: 3 March 2023 (with comments)

Final report issued: 9 March 2023

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: 7 June 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.