Inspection report on compliance with HTA licensing standards
Inspection date: **12 June (remote) and 13 June (site visit) 2024**

Institute of Child Health

HTA licensing number 12220

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 site **Institute of Child Health**	Licensed	Licensed
Satellite site **Zayed Centre for Research into Rare Disease in Children**	Licensed	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 Institute of Child Health ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for Governance and quality systems (change control).

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.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	There was no system to record that staff have read and understood Standard Operating Procedures (SOPs). This poses a potential risk that staff are not following up-to-date procedures. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls 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.	PFE2(c)	The DI is advised to implement a process to regularly test and periodically manually challenge fridge and freezer temperature alarms to provide an assurance that they are operating as expected.
2.	PFE2(c)	The DI is advised to formally implement a system where the temperature plots from the freezer and LN2 monitoring systems are regularly reviewed as this may indicate a potential failure of the units before it occurs.

Background

Institute of Child Health conducts research aimed at enhancing the understanding, diagnosis, therapy, and prevention of childhood diseases. The licensed activity of storing relevant material for scheduled purposes, specifically research, occurs within six tissue collections at the Institute: the Human Developmental Biology Resource (HDBR), the Cardiac Archive, the Living Airway Biobank, the Rare Cardiovascular Diseases Bank, the Childhood Inflammatory Eye Disease Research Bank and the Baby Biobank. A significant portion of the tissue held by the Institute falls outside the licensing scope of the HTA because it is stored for projects that have received ethical approvals from a recognised Research Ethics Committees (RECs).

Institute of Child Health has been licensed by the HTA since July 2007. This was the second inspection of the establishment; the most recent previous inspection took place in June 2011.

Since the previous inspection, the establishment has added one satellite site to the licensing arrangements, appointed a new Corporate Licence Holder contact (CLHc) and DI, and added several Persons Designted (PDs) to the licence.

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

39 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors and PFE2(b) could not be assessed as the establishment does not store bodies or body parts.

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities including equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking system and databases used to record and track relevant material, agreements, audits, and incidents.

Visual inspection

The site visit included a visual inspection of areas where samples were stored, at the hub site and the satellite site. The visual inspection at the hub and satellite site included a review of the areas where RTB material is stored in -80°C freezers, at room temperature (RT), and in Liquid Nitrogen tanks (LN2). In addition, two other laboratories storing relevant material released from the RTB, and using standarised procedures provided by the RTB, were also inspected

Audit of records

During the visual inspection, records for nine samples in storage were reviewed. These samples comprised samples in -80°C freezers (sample to record), stored at RT (sample to record), and in LN2 storage (sample to records). No discrepancies were identified

Meetings with establishment staff

The inspection included discussions with the DI, PDs and other staff working under the licence. This included the biobank manager and representatives of the different research groups working under the licence at the hub and satellite site.

Report sent to DI for factual accuracy: 28 June 2024

Report returned from DI: 03 July 2024

Final report issued: 05 July 2024

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.