Inspection report on compliance with HTA licensing standards
Inspection dates: **22 and 23 May 2023**

Royal Preston Hospital

HTA licensing number 12056

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 Preston 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 Royal Preston Hospital ('the establishment') had met the majority of the HTA's standards, five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

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

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
a) Consent procedures are documented, and these along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	Particular types of tumour tissue may be collected from patients as part of diagnosis and stored in the diagnostic archive. Depending on clinical circumstances, patients may be contacted by Research Tissue Bank staff after samples have been collected to seek consent for research purposes. The tissue remains in the diagnostic archive at all times and will only be released for research once appropriate consent has been obtained. An annual consent audit is carried out on this material. There were no documented procedures or policy positions relating to the management of such samples.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	Staff involved in seeking consent receive regular Good Clinical Practice training (GCP). However, there was no consent training in place which addresses the requirements of the Human Tissue Act 2004.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	There was no formalised process to address actions arising from audits. For example, one audit indicated that a consent form could not be located and it was not clear what corrective actions had been undertaken.	**Minor**

GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	Staff had limited awareness of how to report an incident relating to licensable activities.	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	The procedure that covers disposal of human tissue does not clearly set out the requirements for recording the reason, method and date of disposal.	**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.	C1(a)	The Gastrointestinal tumourbank is overseen by the research nurse who is responsible for collecting, preparing and banking the samples and also entering associated information onto a database. Research Tissue bank staff audit the consent forms every three months but these audits are not documented. The DI should consider documenting these audits to help capture any findings as is carried out for audits in general.
2.	GQ1(a)	The DI should consider creating a a user manual which outlines how to use the traceability system. This will be of particular benefit to new staff.
3.	GQ2(a)	The establishment undertakes an audit of each bank every three months. At present, the audits focus on sample traceability, which include reviewing storage locations, number of samples, whether there is a valid consent form in place and other project related information. The DI may wish to consider reviewing the proforma to include reverse audits from storage to database to assess traceability in both directions.
4.	PFE2(c)	The DI should consider reviewing temperature trends of freezers to identify when storage conditions may be

		deteriorating and to alert staff to developing equipment failure.
5.	PFE2(c)	The procedure 'Management of –80 degrees freezer failure in Neuropathology' includes details on the management of freezer failure during working hours but does not include the procedure for out of hours failure. The DI is advised to review and revise this document to ensure that the out of hours procedure is included.

Background

Royal Preston Hospital operates a number of distinct research tissue banks. This was the second inspection of the establishment; the most recent previous inspection took place in September 2014. The research tissue banks hold ethical approvals from NHS Research Ethics Committees and are managed by two Biomedical Scientists who are responsible for the day-to-day operation of the bank.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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

A number of documents were reviewed, including, policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

No audits were undertaken as part of this inspection, however, the establishment's audit records were reviewed to assess compliance.

Meetings with establishment staff

The inspection included a roundtable with the DI, Research Tissue Bank staff (Biomedical Scientists) and theDeputy Director for Research and Innovation.

Report sent to DI for factual accuracy: 20 June 2023

Report returned from DI: 31 July 2023(with comments)

Final report issued: 31 July 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 December 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.