Inspection report on compliance with HTA licensing standards
Inspection date: **18 April 2023**

Newcastle upon Tyne Hospitals NHS Foundation Trust

HTA licensing number 12193

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 **Newcastle upon Tyne Hospitals NHS Foundation Trust**	Licensed	Not licensed
Satellite site **Balliol Storage Unit**	Licensed	Not licensed
Satellite site	Licensed	Not licensed

North East Innovation Hub		
Satellite site **Freeman 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 Newcastle upon Tyne Hospitals NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and quality systems. The shortfalls related to standard operating procedures (SOPs), audits, and 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.

Compliance with HTA standards

Minor Shortfalls

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.	Each group working under the licence adapts existing SOPs to their activities and equipment. Some SOPs did not provide sufficient details, in that they did not: • describe the process of managing samples held under recognised Research Ethics Committee (rREC) approval to ensure they are transferred to the HTA governance system when rREC approval ends • provide sufficient detail on the process for responding to alarms out of hours • describe the monitoring of Liquid Nitrogen (LN2) storage vessels In addition, establishment documentation indicated that material from the NovoPath Biobank is made available to researchers through a process overseen by a Biobank Access Committee with a specified membership. At the time of the inspection, there was no formal access committee and, while requests for material were approved through a review process, this did not reflect the documented process.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	There was no 2023 schedule of audits covering licensable activities.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	Establishment procedures allow consent to be obtained either in person or by post, under specific conditions, and also allow consent to be sought retrospectively (after tissue has been removed during surgery). Potential risks associated with the different consent-seeking scenarios have not been subjected to a comprehensive risk assessment.	**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.	GQ1(a)	The document NMRB-SOP-020 Disposal of Human Tissue referenced the ‘Human Tissue Act (2004) Code of Practice 5, Disposal of Human Tissue’. The Code of Practice 5 has not been in use since 2017. The DI is advised to review establishment documentation to ensure that references are current.
2.	GQ1(a)	The freezer monitoring systems varied between the different groups working under the licence. The DI is advised to review the procedures outlined in the different SOPs to ensure that they reflect the procedures currently being undertaken by individual groups, and that they meet establishment expectations and requirements.
3.	T1(c)	Several research groups working on the licensed premises routinely work with material held under project specific rREC approval. To improve awareness and oversight of storage requirements for all material held on the licensed premises, the DI is advised to implement a system to record and track the expiry dates of REC approvals. This will allow the DI to be aware of any material coming to the end of its approval so that it can be transferred to the governance of the HTA licence, transferred elsewhere, or be disposed of.
4.	PFE2(c)	The DI is advised to define a temperature range for ambient storage and to implement a monitoring system at Balliol satellite site. This will help to provide assurance that blocks and slides are maintained in suitable storage conditions.
5.	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.

6.	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

Based at the Royal Victoria Infirmary (RVI), the Newcastle upon Tyne Hospitals NHS Foundation Trust is licensed by the HTA under the Human Tissue Act 2004 for the storage of relevant material for use for scheduled purposes. In addition to sample collections held at the NovoPath Biobank and the Newcastle Mitochondrial Research Biobank, samples are also held at the Muscle Immunoanalysis Unit at RVI. The establishment also has three satellite sites, storing relevant material at:

- Central store freezers based at the Freeman Hospital
- The North East Innovation Hub based at the Biosphere, Newcastle
- The Balliol Storage Unit based at the Balliol Business Park.

The majority of relevant material held under the licence is diagnostic material held at -80°C, in LN2 vapour phase storage, or at ambient temperature. In addition to using material sourced from diagnostic archives, the establishment has started to proactively consent patients to donate material for research, and also stores relevant material obtained as surgical remnants, and received from REC approved studies.

Newcastle upon Tyne Hospitals NHS Foundation Trust has been licensed by the HTA since February 2008. This was the second inspection of the establishment; the most recent previous inspection took place in November 2014.

Since the previous inspection, the establishment has added three satellite sites to the licence, appointed a new DI, and added several Person's Designated (PDs) to 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
There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not store bodies or body parts (standards published 3 April 2017).

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 consent procedures and template consent forms, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking spreadsheets and databases used to record and track relevant material, agreements, audits, and incidents.

Visual inspection
No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the storage facilities at the hub and satellite sites that allowed an assessment of security around the storage units and the signage on the individual units.

Audit of records
Three recent internal audits were reviewed as part of the inspection. This was in addition to a review of a recent audit of human tissue holdings across the Trust.

Meetings with establishment staff
The inspection included discussions with the DI and other staff working under the licence. This included Quality Assurance representatives from the Newcastle Joint Research Office, Quality Managers from groups working under the licence, a clinical tirals associate and other staff involved with seeking consent, a Research Biomedical Scientist, and PDs representing each group holding relevant material under the licence.

Report sent to DI for factual accuracy: 16 May 2023

Report returned from DI: 30 May 2023

Final report issued: 12 June 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: 5 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.