Inspection report on compliance with HTA licensing standards
Inspection date: **25 to 28 April 2022**

Norfolk and Norwich University Hospital

HTA licensing number 11208

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Norfolk and Norwich University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-
Satellite sites **The Cotman Centre**	-	-	Carried out

The Norwich Biorepository	-	-	*Carried out*

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 Norwich University Hospital ('the establishment') had met the majority of the HTA's standards, five major shortfalls were found against standards for Governance and quality systems and Traceability.

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

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	SOPs MORT-035 and 037 do not detail the use of three identifiers for viewing of the deceased. *Refer to the shortfalls against GQ6b and T1c for further detail.*	**Major**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
e) The establishment adopts a policy of candour when dealing with serious incidents.	Whilst staff know how to report incidents to the HTA, examination of the mortuary incident log identified one incident relating to a near miss security breach; this had not been reported to the HTA.	**Major**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Risk assessments relating to the Norwich Biorepository cover health and safety risks but do not address risks in relation to human tissue. The risk assessment relating to viewing of the deceased does not include sufficient mitigating controls such as the use of three identifiers to reduce the risk of viewing of the wrong body. *Refer to the shortfall at T1c for more detail.*	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased, provided by relatives, against the identification on the body before a viewing takes place. This poses a risk of viewing of the wrong body.	**Major**

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises	The assessment team observed a funeral director's release. It was identified that some funeral directors attending do not arrive with the three identifiers required to ensure traceability.	**Major**

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 practice:

Number	Standard	Advice
1.	GQ2 (c)	Tissue Audits – whilst all tissues selected for audit by the inspection team were fully traceable at the Cotman Centre, the DI is advised to add a tissue traceability audit to the audit schedule.
2.	GQ6 (a)	Some risk assessments and policies refer to 'next of kin'. The DI is advised to update these to 'person highest in qualifying relationship or nominated representative'.
3.	PFE1 (c)	The premises were clean. The DI is advised to create an SOP to include cleaning schedules to reflect practice.
4.	PFE2 (a)	Condition checking of bodies is taking place. The DI is advised to create an SOP to reflect practice.
5.	PFE2 (e)	All fridges are alarmed. The DI is advised to ensure fridge alarms are challenge tested at the Norfolk Biorepository site.
6.	PFE2 (e)	Fridge units are in good working order. The DI is advised to review temperature trends for the -80ºC storage units at the Norfolk Biorepository, as they are not currently under a maintenance contract.

Background

Norfolk and Norwich University Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent inspection took place in October 2016.

Since the previous inspection, there has been some significant changes to the licence arrangements including the change of Designated Individual (DI). There are also plans to apply for a separate research licence for the Norfolk Biorepository due to the expansion of this facility.

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 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI and Mortuary Manager in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation, and equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the hub and two satellite premises which included the mortuary body storage areas, the PM suite as well as the storage arrangements for relevant material held within the facilities.

Audit of records

The inspection team undertook audits of traceability for six bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified. Audits were conducted of stored material at Norfolk Biorepository for three cases. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, an Anatomical Pathology Technologist (APT), a senior porter, staff at the Biorepository satellite site, staff involved in the consent seeking processes and the DI.

Report sent to DI for factual accuracy: 19/05/22

Report returned from DI: 1/06/2022

Final report issued: 6/06/2022

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: 6 October 2022

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 both the draft and 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.