Inspection report on compliance with HTA licensing standards
Inspection date: **17 & 18 October 2023**

Doncaster Royal Infirmary
HTA licensing number 12268

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 **Doncaster Royal Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site **Bassetlaw Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*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 Doncaster Royal Infirmary ('the establishment') had met the majority of the HTA's standards, two major and four minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

Shortfalls against HTA standards C2(b) and C2(d) relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

Concerns were discussed with the establishment as part of this inspection. The DI has provided assurance that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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
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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The establishment did not have an SOP for the seeking of consent for perinatal post mortem (PM) examination which details the process for those seeking consent.	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The establishment had not undertaken the consent seeking process for adult PM examination for approximately five years. As a result, training has lapsed meaning there were no recent records of training for those who would seek consent if it was requested. Whilst the bereavement midwives have undertaken consent seeking training for perinatal PM examination and this is recorded, there was no record of training for doctors within the maternity department who also seek consent although assurance was provided that training had been completed.	**Major (Cumulative)**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	As there was no process in place for the recording of all consent trained individuals within the maternity department, assurance could not be provided that untrained staff are accompanied by a trained individual in all cases where consent is sought for perinatal PM examination.	
d) Competency is assessed and maintained	Competency had not been assessed or maintained for both adult and perinatal consent seekers.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst regular meetings were held with mortuary and laboratory staff working under the licence, Persons Designate (PDs) from maternity or the Emergency Department were not invited to governance meetings.	**Minor**

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	Whilst risk assessments were in place which covered the majority of the licensed activities, not all potential risks to the deceased had been considered or reflected control measures in place. (see *Advice* item 4)	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	Whilst the premises were clean at the time of the inspection there were some areas of damage to walls in the body stores and changing rooms at the satellite site exposing porous plaster and radiators with large areas of peeling paint. This means these areas may be difficult to effectively clean and decontaminate.	**Minor**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst infrequently used by visitors to access the mortuary, the porters access door at the hub site did not have any security measures in place for staff to know who was at the door prior to opening it. Furthermore, whilst families are accompanied by staff when requiring access to the viewing room, this door also did not have security measures in place for staff to know who was at the door prior to opening it. This may risk unauthorised access to the mortuary if unexpected visitors arrive to these doors and staff security is compromised.	**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 practice:

Number	Standard	Advice
1.	C1(a)	Whilst the overarching consent policy refers readers directly to the HTA Codes of Practice to fully understand the requirements of the HT Act and HTA Codes of Practice, the link to HTA information in the policy was broken. The DI is advised to ensure the policy is fully reflective of requirements of the HT Act and the HTA Codes of Practice to ensure information continues to be available in the event links to supporting information do not function.
2.	C1(e)	The DI is advised to liaise with the Coroner service in relation to the family wishes form used for retention or disposal of material retained at PM examination: • The form currently only details two identifiers of the deceased which is name and date of death. This poses a risk to tissue / organs not being managed in line with the wishes of families where there are deceased with the same or same similar name who may have died on the same day. • The form does not list or provide sufficient detail of all the relevant scheduled purposes as defined by the HT Act that those giving consent to retention and use of material can consent to. • The form does not have an area to include the relationship to the deceased of the person giving consent. The relationship had been entered by Coroner's officers in most cases on an ad-hoc basis. However, to ensure consistency and so the establishment can be assured the person providing consent is the most appropriate person to do so, it is advisable for the form to require this information to be captured. The DI is also advised to liaise with the Coroners service and pathologist(s) undertaking PM examination to ensure information provided to families on the retention of tissue at Coroner PM

		examination is fully reflective of the amount of tissue retained. The family wishes form infers that 'stained slides' have been taken for retention or disposal, however, in practice pathologist(s) may take larger blocks or larger organ sections which are then trimmed down during tissue processing to create small blocks for analysis which can also be retained or disposed of.
3.	GQ3(a)	Training was provided to porters on mortuary security measures, HTARI reporting and expected behaviour in the mortuary however, this is not fully recorded in the porter training document. The DI is advised to update the training document to fully reflect the training that has been provided.
4.	GQ6(b)	The DI is advised to review the HTA reportable incident (HTARI) categories against risk assessments in place to ensure that all HTARI risks have been fully considered and mitigated.
5.	PFE2(e)	Whilst fridge and freezer alarm testing was incorporated into the audit schedule, the DI is advised to include an out of hours fridge and freezer alarm test on a regular basis to ensure the out of hours procedures work as expected.
6.	N/A	The PM room at the satellite site has now been repurposed into additional body storage fridges. The satellite site is still licensed for the activity of PM examination. The DI is advised to review this arrangement as the activity of PM examination could no longer be undertaken at this site - How to make changes to your licence | Human Tissue Authority (hta.gov.uk).

Background

Doncaster Royal Infirmary has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment; the most recent previous full routine inspection took place in July 2018. A targeted unannounced inspection was undertaken in May 2023.

Since these previous inspections, there has been an extension to the premises (increase in fridge and freezer storage capacity) in June 2020 and May 2022 and a change to the role of the DI took place in July 2019.

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 in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records, including induction records of visiting staff. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at the hub site and satellite site which included the mortuary body storage areas, the PM room at the hub site, the viewing rooms, the laboratory where tissue retained at PM is stored at the hub site and the maternity department at the hub site.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at both the hub and satellite site. This included bodies with same / similar names and a body in frozen storage. Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, associated records of the deceased and the mortuary register. No discrepancies with traceability were identified.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, the laboratory tissue spreadsheet and the wet tissue and tissue blocks and slides being stored. Two cases were identified as being stored for a scheduled purpose with appropriate consent

and two cases had been disposed of in line with the wishes of the family. One case was awaiting further examination and analysis by the pathologist. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence including members of mortuary staff, the mortuary and laboratory manger, members of the portering staff, staff involved in the consent seeking process for perinatal PM examination, a visiting pathologist who undertakes PM examination, the quality manager, and the DI.

Report sent to DI for factual accuracy: 14 November 2023

Report returned from DI: 28 November 2023

Final report issued: 04 December 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 March 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 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.