Site visit inspection report on compliance with HTA licensing standards
Inspection date: **24 – 26 September 2019**

Queen's Medical Centre

HTA licensing number 12258

Licensed under the Human Tissue Act 2004

Licensed activities

Hub and satellite site rows denote whether the site is licensed to carry out an activity; the rows below the hub and satellite rows denote whether or not the activity is currently carried out in that area.

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 **Queen's Medical Centre**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	*Carried out*	-

Accident and Emergency (A&E) department	-	*Carried out*	-
Museum	-	-	*Carried out*
Satellite site City Hospital	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Maternity department	-	*Carried out*	-
National Repository Centre	-	-	*Carried out*
Tissue Biobank	-	-	*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 Queen's Medical Centre (the establishment) had met the majority of the HTA's standards, ten major and nine minor shortfalls were found against standards for Consent, Governance and Quality, 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

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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	National Repository Centre There is no consent policy covering the activities of the National Repository Centre, including the requirements for: • seeking consent for donation of bodies or tissue; • accepting donations from referral centres; and • ensuring that bodies and tissues are stored and used in accordance with the consent given. The establishment cannot provide assurance that specimens have not been used outside the consent given. Some Material Transfer Agreements (MTAs) for specimens sent from the National Repository Centre to requesting establishments state that specimens are to be used for the scheduled purpose of anatomical examination, despite consent having not been given for this scheduled purpose.	**Major**

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	<u>Maternity</u> The consent seeker guidelines described on the consent form for babies who are stillborn or who die shortly after birth do not fully reflect the requirements of the HT Act and the HTA's code of practice. The guidelines on the consent form state that the father can give consent if he is married to the mother. <u>National Repository Centre</u> The inspection team's body audits found two consent forms had not been completed fully. This means that the establishment cannot be assured of the donor consent wishes for these bodies. Specimens from these bodies had been sent to requesting establishments for use for a scheduled purpose. This poses a risk that specimens may be stored and used without appropriate consent.	**Major**
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.	Some standard operating procedures (SOPs) do not reflect current practice or do not contain sufficient details of procedures. For example: <u>Mortuaries</u> • PR1873' Patient Transfer and Viewing Arrangements': o The SOP does not consistently state that a minimum of three identifiers should be used for the identification of bodies for release from the mortuary. o The SOP states that only two identifiers of the deceased need to be checked prior to transferring the body to the viewing room at the satellite site. • PR1874 'Mortuary Administration Procedures': o The SOP does not describe the procedure for contacting the Coroner when no information is received about the family wishes for the fate of samples or when the Coroner's authority has ended.	**Major**

	National Repository Centre • There is no documented procedure to check the consent wishes of the donor at the time of accepting a body donation. NUN-NNRC-012 'Repository Administration' refers to out of date consent forms. Tissue Biobank • NHSBSOP2 'Sample production, storage and disposal process' does not describe the procedure to follow if forms or labelled specimens received do not meet the accepted criteria listed in the SOP.	
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedules for licensed activities conducted under the licence is limited. The audit schedules do not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues.	**Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	National Repository Centre Audit findings and recommendations do not state who is responsible for the root cause analysis and implementing corrective actions, or give a date of completion for findings. Tissue Biobank Audit findings for the tissue biobank have not been investigated fully to understand the root cause of failures to comply with the establishment's procedures.	**Major**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	National Repository Centre Audits of consent forms are not carried out to ensure that bodies are being stored and used in line with the consent given by the donor, including any restrictions on the period of retention. Tissue Biobank The establishment could not provide evidence of consent for storage of samples from one project in the tissue biobank.	**Major**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	<u>Mortuary</u> Risk assessments relating to licensed activities in the mortuary do not fully consider the risks to bodies and tissues. SR466 'Patient Transfer and Viewing' does not include the risks of viewing of a wrong body, release of a wrong body and accidental damage to a body. <u>Tissue Biobank</u> Risk assessments relating to licensed activities in the tissue biobank have not been reviewed regularly. The risk assessments were last reviewed in April 2017.	**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 establishment's procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • For release of bodies from the mortuary, staff print documents which only contain two identifiers of the deceased. Identification of bodies for release from the mortuary to funeral directors may be performed using only one or two identifiers provided by the funeral directors. • Relatives are only required to provide one identifier of the deceased when they attend the mortuary for a viewing.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	National Repository Centre The trays used in the body store are not large enough for the size and number of specimens that are stored on them. Some specimens are stored directly on the base of the freezer unit. These storage arrangements pose a risk of accidental damage to specimens and a risk to the dignity of the deceased.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have sufficient freezer storage capacity to meet the need for long-term storage of bodies. At the time of the inspection, mortuary staff had identified that a number of bodies in refrigerated storage had deteriorated in condition and required freezer storage. This poses a risk to the dignity of the deceased.	**Major**

Minor 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	National Repository Centre The SOP for seeking consent for donations to the National Repository Centre references 'Next of Kin'. There is a risk that the establishment could obtain consent from a person who is not the appropriate person defined by the HT Act. Tissue Biobank SOPs NHSBSOP1 and NHSBSOP7 reference consent forms that are no longer in use and a previous version of the HTA code of practice on consent.	**Minor**

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	<u>Mortuary</u> Staff training records for seeking consent for adult PM examination are not documented. <u>Tissue Biobank</u> Staff training records for seeking consent and donation of samples to the tissue biobank are not documented.	**Minor**
d) Competency is assessed and maintained	There is no reassessment of competency to seek consent for staff who seek consent for paediatric PM examinations or donation of samples to the tissue biobank.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team's audit found that the establishment's procedure for checking and documenting the condition of bodies is not followed consistently.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
d) Information about incidents is shared with all staff to avoid repeat errors	Relevant information about incidents is not always shared with portering staff who undertake activities in the mortuary. The portering team is not represented at governance meetings relating to the HTA licence.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The inspection team's tissue traceability audit found that some tissue slides stored at Queen's Medical Centre were not recorded in the electronic database when transferred to another establishment.	**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	The mortuaries at Queen's Medical Centre and City Hospital are showing signs of wear and require some maintenance to remain fit for purpose. There are multiple areas of damage to walls and doors, leading to exposed porous plaster and wood. This means that these areas are difficult to clean and disinfect adequately. The inspection team's visual inspection of the PM room at Queen's Medical Centre found that some areas of the facility had not been cleaned to an appropriate standard. There were blood spots on the dissection sinks and hair on the floor.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	<u>Mortuaries and National Repository Centre</u> The temperature alarm trigger points for the fridges and freezers are not set at appropriate temperatures to ensure that the alarms will trigger when storage temperatures deviate from acceptable ranges.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The hoists at City Hospital have multiple areas of rust. This means that it is difficult for staff to adequately clean and disinfect this equipment.	**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.	GQ1(a)	The DI is advised to ensure that references to documents and resources in the establishment's policies and procedures are up-to-date. This includes ensuring that references to the HTA codes of practice and standards are to the most recent versions.
2.	GQ1(d)	The DI is advised to ensure documents are authorised by a person other than the author. SOP PR1974 'Standard Post Mortem Examination Process and Related Procedures' was written and authorised by the same person.
3.	GQ3(a)	The DI is advised to review training for staff who undertake licensed activities to ensure that they have sufficient knowledge of the requirements of the HT Act and the HTA's codes of practice that are relevant to their work.
4.	PFE1(d)	The DI is advised to consider options to enable staff to see visitors who request access to the mortuary by the hospital entrance at City Hospital.
5.	T1(g)	The DI is advised to continue to catalogue the potted specimens stored at Queen's Medical Centre for teaching pathology to medical students.

Background
Queen's Medical Centre is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Queen's Medical Centre has been licensed by the HTA since August 2007. This was the third site visit inspection of the establishment; the most recent previous inspection took place in June 2016.

<u>Mortuary</u>
There are two mortuaries under the licence at Queen's Medical Centre and City Hospital. Mortuary processes have been aligned between the sites. PM examinations are conducted at the Queen's Medical Centre mortuary.

National Repository Centre

The National Repository Centre at City Hospital accepts body donations for the purpose of education and training relating to human health. Specimens may be transported to other establishments.

Tissue Biobank

There is a research tissue bank stored under the licence at City Hospital. The tissue biobank has approval from a research ethics committee.

Museum

A large number of potted specimens are stored at Queen's Medical Centre. The specimens are used for teaching pathology to medical students.

Since the previous inspection, there have been no significant changes to the licence arrangements; however, the level of activity carried out under the licence at the National Repository Centre has increased significantly.

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 for the PM sector were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM rooms, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection included a visual inspection of all areas covered by the licence at the hub site and satellite site. Visual inspection of Queen's Medical Centre included the mortuary body store, PM rooms, viewing room, A&E department, maternity department and the pathology

laboratory. The visual inspection of City Hospital included the mortuary body store, viewing room, tissue biobank and National Repository Centre body store.

Audit of records

Mortuary

Audits were conducted for eleven bodies in refrigerated storage; seven bodies at the hub site and four bodies at the satellite site. Body location and identification details on the bodies were crosschecked against the information recorded in the mortuary database.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. Discrepancies were found in two cases relating to misplaced slides.

National Repository Centre

Audits were conducted for four bodies in freezer storage at the National Repository Centre. Body location and identification details on the bodies were crosschecked against the information held at the repository. Audits of traceability were conducted for four bodies sent to other establishments, including MTA and consent documents. Discrepancies on consent forms and MTAs were found.

Tissue Biobank

Audits of traceability were conducted for eight samples; two samples stored at -80°C, two slides stored at room temperature and four tissue samples stored in liquid nitrogen. Consent documentation for the use and retention of these tissues was checked; full traceability could not be checked at time of audit for samples stored in liquid nitrogen. The establishment subsequently provided the consent forms to complete the traceability audits.

Museum

Audits of traceability were conducted for five samples; three potted specimens and two formalin-fixed organs. Location and identification details were crosschecked against the electronic database.

Meetings with establishment staff

Staff carrying out processes under the licence at both sites were interviewed including the DI, Anatomical Pathology Technologists, a pathologist, portering staff, maternity staff, A&E department staff, tissue biobank staff, National Repository Centre staff and an adult consent seeker.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 06.11.2019

Report returned from DI: 15.11.2019

Final report issued: 22.11.2019

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.