Site visit inspection report on compliance with HTA licensing standards

Southmead Hospital

HTA licensing number 12413

Licensed under the Human Tissue Act 2004 for the

- **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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

12th – 14th September 2017

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

Although the HTA found that Southmead Hospital met the majority of the HTA's standards, a total of thirteen major and five minor shortfalls were found against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to policies and training for hospital (consented) post mortem examinations; governance meetings, risk assessments and audits; competency assessments; release of bodies; fridge and freezer maintenance and alarms; post mortem room ventilation and security respectively.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual 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 Designated Individual 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.

Background to the establishment and description of inspection activities undertaken

Southmead Hospital (the establishment) is part of the North Bristol NHS Trust (NBT) and holds HTA licences for the Human Application and Post Mortem (PM) sectors. This report covers an inspection of their PM sector licences under the Human Tissue Act 2004 (HT Act) for: carrying out PM examinations; removal from the body of a deceased person of relevant material (for scheduled purposes),and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. In addition to the mortuary, licensed activities are carried out in other areas at the establishment, which are under the governance and supervision of the DI for the PM sector licence. St Michael's Hospital mortuary is the satellite of the establishment. The Corporate Licence Holder contact is the Medical Director for the Trust; the Designated Individual (DI) is the Cellular Pathology Laboratory Manager.

The establishment has been licensed by the HTA since March 2007. Previous site visit inspections took place in November 2010 and September 2014, the most recent of which was undertaken jointly with UKAS. This report describes the third site visit inspection, in September 2017. Formal interviews were conducted with the DI, mortuary staff, portering supervisor, Consultant Paediatric Pathologist, perinatal PM consent seeker, Consultant Neuropathologist, Consultant Urology Surgeon and laboratory staff involved in all activities covered by the licence. Visual inspections of areas where tissue is stored and of both mortuaries, including the body stores, viewing suites and post mortem room (St Michael's Hospital only) were also undertaken.

Southmead Hospital Mortuary

The mortuary at Southmead Hospital (the hub), located in the Brunel Building, operates as a body store only for adult cases, paediatric cases, fetuses and products of conception (POC) from the hospital. Bodies from the community are not admitted to the mortuary. Adult bodies requiring a PM examination are transferred to another HTA-licensed establishment. However, there is an appropriate room for the removal of tissues by retrieval teams adjacent to the body store.

The mortuary receives approximately 1900 bodies each year from the hospital. Deceased patients are transferred to the mortuary from the wards by porters using a concealment trolley via lifts to the staff corridor leading to the mortuary. Porters admit all bodies to the mortuary and complete the 'porter register', then enter the name of each body on to the allocated fridge door (see *Advice*, item 30). POC paperwork is placed in to a dedicated file, which mortuary staff check daily. Mortuary staff complete patient identification checks and the admission process as soon as possible on the day, or the next working day if the body was admitted out of hours, using a triplicate 'Notification of Death' (NOD) form transferred with each body. Mortuary staff complete an 'audit checklist' and the mortuary register for each body (see *Advice*, item 29). Training in mortuary procedures is provided by the

mortuary staff to the porters. This is recorded, competency assessed and refreshed when required (see *Advice*, item 24).

Although hospital (consented) post mortems (adult and paediatric/perinatal) are not carried out at the establishment, consent for these cases is sought on site by clinicians who do not receive training in seeking consent for adult PM examinations but may have had some training in relation to seeking consent for paediatric/perinatal cases (see shortfall against C2(a)). The consent forms used by the establishment for adult consented PM examinations are based on the HTA's model consent forms, and the SANDs consent form is used for paediatric/perinatal cases, and are therefore compliant with statutory and regulatory requirements.

The establishment has 54 refrigerated spaces and four freeezers for the storage of bodies. This includes spaces for bariatric and super-bariatric cases. There are two dedicated fridges for the storage of paediatric/perinatal cases and POC (see shortfall against PFE2(e)). The POC fridge was noted to be running at around seven degrees and above during the visual inspection (see *Advice,* item 39). The trigger points for the alarm of the main fridge unit was not set to acceptable limits (-1°C and 15°C) and the timescale before the alarm would trigger was unknown (see shortfall against PFE2(a)). At the time of inspection, there were three temporary refrigerated Nutwell units housed within a concealed and secure external area close to the mortuary. Although these were in operation, no bodies were currently being stored in them. In addition, they are not connected to an alarm (see shortfall against PFE2(e)). The Nutwell units have been in use during peaks of activity and the establishment has agreements with other local establishments and funeral directors for further contingency storage (see shortfall against GQ1(a)).

Authorised swipe card access is required for all external doors in to the mortuary and there is a camera and intercom system, allowing mortuary staff to see and speak to any visitors and funeral directors prior to granting access.

Bodies are released to funeral directors using a release form given to relatives when they visit Bereavement services; other release forms and the green disposal form will also be accepted (see shortfall against T1(c)). Notification that a body is for Coroner's PM examination and requires release to another establishment is sent by the Avon Coroner to the mortuary. All bodies are signed out in the mortuary register. Fetuses for group cremation are checked by the mortuary and chaplaincy staff against paperwork before they are released to the contracted funeral director for cremation.

The mortuary has one full time Anatomical Pathology Technologist (APT), one full time mortuary assistant and a mortuary/laboratory assistant who provides cover at both the hub and satellite sites, when required. At the time of the inspection, the mortuary assistant is the only permanent member of staff and can often work alone. In addition, mortuary staff work on-call, predominantly for the preparation and carrying out of all viewings. The risks of lone

working within the mortuary have been assessed by the hospital security team, resulting in the recommendations to install panic alarms, which have yet to be actioned (see *Advice*, item 38). There are currently two members of staff on call, only one being the full time mortuary support worker, the other is a bank member of hospital staff. The DI provides cover when necessary for all mortuary activities (see shortfall against GQ3(c)).

The maternity unit at the hospital has a fridge for the storage of fetuses and neonates prior to transfer to the mortuary (see shortfall against PFE2(e)). Transfer of these cases to the mortuary is by the porters and arranged by the maternity unit staff (see *Advice*, item 31).

An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for three adult bodies (one body from the freezer) and three perinatal bodies. In relation to the adult bodies, issues were identified with the spelling of the last name of one case on the fridge whiteboard and the address details in two cases; one being a result of the carbon copy of the NOD form being unclear; the other being a spelling error in the mortuary register. The three perinatal bodies have been in refrigerated storage at Southmead Hospital mortuary since before the HT Act came into force. In one case, there wasn't any identification details on the body, only on the small box the fetus was contained in. The mortuary does not have any documentation in relation to these bodies from the time they were admitted to the mortuary or subsequently to demonstrate any follow-up of these cases. All three fetuses were buried the week following this inspection.

St Michael's Hospital Mortuary

St Michael's Hospital (the satellite) is a women's and children's hospital located on University Hospitals Bristol NHS Foundation Trust (UHBFT) grounds; therefore, the premises are managed by UHBFT. The mortuary at St Michael's Hospital is located in the main hospital building. The governance of the mortuary and employment of the mortuary staff is managed by the establishment.

St Michael's Hospital mortuary stores paediatric bodies, perinatal bodies and POC from the hospital. Paediatric/perinatal cases for hospital (consented) PM examinations are transferred to St Michael's Hospital from the hub and other hospitals in South West England. Occasionally, adult hospital (consented) PM examinations, and brain and/or spinal cord harvests, are requested at the hub and from Bristol Royal Infirmary; these cases are also transferred to St Michael's Hospital mortuary. In addition, the mortuary staff carry out the 'cut-up' procedure for all placentas from the maternity unit before sending them to the hub for processing in histopathology. This task was not originally undertaken in the mortuary and has increased workload at the same time that staffing levels have reduced.

Three paediatric/perinatal pathologists (although there is currently one vacancy) perform approximately 280 hospital (consented) PM examinations at St Michael's Hospital each year. Consent for perinatal and paediatric cases is undertaken by clinicians who may have had

some training in relation to post mortem consent (see shortfall against C2(a)). The SANDs consent form is used for paediatric/perinatal cases, which is compliant with statutory and regulatory requirements (see *Advice*, item 12). In addition, the 'Perinatal Post Mortem Request Form' must be completed by the clinicians to provide additional medical information that may be relevant to the PM examination (see *Advice*, item 13).

Tissue removed for histopathological analysis during PM examinations is recorded on the 'Post Mortem Tissue' form and sent to Southmead Hospital for processing and examination, by the paediatric pathologists. The transfer of PM samples is recorded in a dedicated book for this purpose. All blocks and slides are managed in accordance with the relatives' wishes at the hub site or returned to the mortuary at St Michael's Hospital for return with the body or to the funeral director (if required).

The mortuary is staffed by two permanent APTs (one full time and one part time) and a mortuary/laboratory assistant, who provides cover at both the hub and satellite sites, when required. Lone working occurs frequently and some of the mortuary staff work on-call, also covering the body store at UHBFT. There is no SOP for lone working and the risks of lone working have not been assessed (see shortfalls against GQ1(a) and GQ6(a)).

The establishment has six refrigerated body spaces and three freezer spaces, all of which can accommodate adult bodies; therefore, more than one paediatric/perinatal case can be placed on the same tray (see *Advice*, item 43). The upper trigger point for the alarm was not set to an acceptable limit (10°C), the lower trigger point and the time scale before the alarm would trigger was unknown (see shortfall against PFE2(a)) and the alarms are not regularly tested (see shortfall against PFE2(e)). In addition, it could not be established when the fridges were last serviced and records were not available for review (see shortfall against PFE3(f)).

In addition, within the body store, there is a -80°C freezer that was transferred from the mortuary at Bristol Royal Infirmary. The inspection team were informed the freezer contains specimens which are 'existing holdings' (specimens that were already being held for use for scheduled purposes when the Act came into force on 1 September 2006). The freezer is in a state of disrepair, threatening the integrity of the specimens held in there and there is currently no easily accessible records of the freezer contents (see *Advice*, item 50).

The mortuary's PM suite contains a single PM table and two dissection benches. In addition, there is a X-ray machine that only trained APTs are authorised to use. The pathologist and APTs carry out identification checks of bodies prior to PM examinations and the pathologist is required to sign the 'UHB Face Sheet Fetal & Perinatal Post Mortem' form to confirm they have checked the PM consent form and identification of the body. A 'one-at-time' system is used to avoid mix-up of organs and tissue samples removed during PM examinations. Although the PM suite ventilation system is working, it has not been serviced or maintained (see shortfall against PFE3(c)).

Key access is required for both external doors in to the mortuary. Keys are restricted to mortuary staff, porters and the paediatric pathologists. There is an intercom system at each door; however there is no camera or CCTV coverage (see shortfall PFE1(d)).

St Michael's Hospital has a maternity unit and gynaecology wards. There is a fridge for the storage of fetuses and neonatal bodies on the maternity unit prior to transfer to the mortuary (see *Advice*, items 41 and 42).

Porters admit all paediatric bodies in to the mortuary from the hospital. The mortuary staff are responsible for transferring and admitting all perinatal bodies into the mortuary from the maternity unit. Documentation sent with each body includes information to cross reference the identification on the body and the disposal wishes of the mother/parents. On admission to the mortuary, the 'porter register' is completed by the porters or the mortuary staff. In addition, the name or 'baby..<name>..' is written on to the allocated fridge door (see shortfall against PFE1(a) and *Advice*, item 30). The mortuary register and a 'Body Record Sheet' is completed for each body by the mortuary staff, once body identification and condition checks have been completed. The mortuary staff are responsible for admitting bodies transferred from other hospitals.

The mortuary has a database for recording all bodies admitted to the mortuary and other hospital software programmes that require completion for various functions to be carried out; for example, ordering of X-rays. Mortuary staff reported this was quite time consuming and they are often interrupted during this process (especially when lone working), potentially leading to transcription errors or not completing processes altogether (see *Advice*, item 45).

Bodies are released from the mortuary using a release form from the funeral director and the green disposal order, often only stating two identifiers (see shortfall against T1(c) and *Advice*, item 11). Contracted funeral directors transfer bodies between certain hospitals and St Michael's, and often use a tracking document to record these transfers (see *Advice*, item 35).

During the visual inspection, it was noted by the inspection team there were numerous areas of flaking paint and exposed plaster within the post mortem room, body store and ancillary areas (see shortfall against PFE1(a)). In addition, the body measure used for adults is made of wood (see *Advice* item 44).

An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for three perinatal bodies transferred to the mortuary for hospital (consented) PM examinations. Issues were found in relation to the identification labels in two of the cases. The labels of one case were safety-pinned to the blanket the fetus was wrapped in; no identification was on the fetus itself (see *Advice*, item 28). The labels in the second case had no identifying details on them. Although these were visible on

admission, the labels had become wet, blanching the ink. This fetus had a unique reference number printed on the ID bands and on the box from the referring hospital, but this wasn't recorded by the mortuary staff on admission, therefore not on any of the mortuary paperwork (see *Advice*, item 32). In addition, audits of four PM examination cases, where tissue had been removed, were conducted (three perinatal hospital (consented) cases and one adult (consent) brain 'harvest', for research). The consent forms and documentation were reviewed for the three perinatal cases to establish the relatives' wishes for the tissue and if these had been complied with. Some anomalies were found. The number of slides in two of the cases were not recorded on the 'Post Mortem Tissue' form, although this information was entered on the laboratory computer system and was correct. The consent form in relation to one case indicated that a full PM examination and an external (non-invasive) examination were required. There was no supporting documentation with the consent form to confirm this had been followed up and checked prior to the full PM examination taking place (see shortfall against GQ1(a)). The consent form for the consented brain harvest (from 2016) was still with the pathologist who is not based on site; therefore, the consent form could not be reviewed (see *Advice*, item 12).The establishment is required to complete this audit and provide evidence to the HTA.

Neuropathology Department

The Neuropathology Department is located in the Pathology Sciences Building at Southmead Hospital. The department houses a collection of formalin-fixed brains and tissue blocks and slides from coronial and hospital (consented) PM examinations with consent for use for research. This collection was transferred from the Frenchay Hospital in 2015, when the hospital was closed. The department conducts an annual review of all specimens within the collection. Release of tissue to researchers is coordinated via a third party (BRAIN UK) and released under material transfer agreements (MTAs).

Traceability audits of four specimens were conducted. Details were taken from documentation and compared with the electronic records and tracked to the collection storage area within the neuropathology archive. No anomalies were found.

The Brain Tumour Bank South West (BRASH) is based in neuropathology and stores blood and tumour specimens from living patients. All specimens are assigned a unique number and stored in a secure room, in a locked -80°C freezer, which is remotely alarmed and monitored. On-call staff are alerted to any issues and samples can be moved to a contingency freezer in the event of a breakdown (see *Advice*, item 40). BRASH has research tissue bank (RTB) approval from a recognised research ethics committee (REC; Welsh REC 3). Consent is sought by trained advanced nurse practitioners during clinical appointments. These nurses work closely with the staff in BRASH (see *Advice*, items 3 and 4). All applications from researchers requesting tissue are reviewed by the Brain Tumour Bank Committee, and specimens are released, de-identified, under MTAs.

Traceability audits of five specimens were conducted. The consent forms of all specimens were reviewed, checked against information on the electronic record and tracked to the storage locations within the freezer. No anomalies were found.

Bristol Urology Institute (BUI) – Urology Research Tissue Bank

The Bristol Urology Institute is located in the Learning and Research Centre at Southmead Hospital. The Urology Research Tissue Bank has research tissue bank (RTB) approval from a recognised research ethics committee (REC; South West Frenchay) but is not currently storing any tissue, although this will happen in the near future. The processes in relation to obtaining consent, the storage arrangements for tissue and documentation were reviewed (see *Advice*, item 7). Fresh blood, bladder and prostate tumour specimens will be stored in a secure -80°C freezer (see *Advice*, items 40 and 41). Wax blocks will be stored in a secure cupboard within the BUI, accessible only to research tissue bank staff. Consent will be sought by trained specialist nurses and consultant urology surgeons during pre-operative clinical appointments (see *Advice*, items 3 and 4). All applications from researchers requesting tissue will be reviewed and approved by the Urology Tissue Bank Committee. Specimens would be released, deidentified, under MTAs (see *Advice*, item 21).

Respiratory Research Laboratory

The Respiratory Research Laboratory is located in the Clinical Research Centre at Southmead Hospital. Blood and pleural fluid samples from patients participating in clinical research trials are stored in a secure –80 ^{o}C freezer in the Learning and Research Building. Donor consent is sought by consultant clinicians or research nurses. The majority of samples are stored for research projects with favourable opinion from NHS RECs; therefore, their storage is exempt from the HT Act's licensing requirements. Samples collected for research projects where ethical approval has expired are stored under the PM sector licence.

Audits were conducted of five samples held under the licence. This included review of documentation, electronic records and tracking specimens to their location in storage. One anomaly was found, where a number had been mistyped into the database spreadsheet. Regular audits of the information on the spreadsheet versus samples in storage and the consent forms are not undertaken (see shortfall against GQ2(a)).

Toxicology Laboratory

The Toxicology Laboratory is located in the Pathology Sciences Building at Southmead Hospital. The laboratory receives post mortem blood, vitreous humour and urine specimens from different establishments (and Coroner's jurisdictions) for routine Coroner's and forensic PM examinations. Specimens are dealt with in a secure preparation area within the

laboratory and assigned a unique ‘case number’. Barcoded stickers are used on the specimens displaying this number before they are analysed.

The laboratory receives tissue forms from the relevant Coroner’s Offices, stating the family’s wishes for the tissue once the Coroner’s authority has ended. There is a documented procedure for ‘chasing-up’ outstanding tissue forms and the process for dealing with samples (BS/CB/LM/OFFICE/10 Disposal of FT samples/HTA Next of Kin Forms/Inquest Dates) (see *Advice*, item 2). All specimens are kept refrigerated (4 ^{o}C) prior to testing and are stored in freezers (-20 ^{o}C) after testing. The fridges and freezers are remotely monitored, alarmed and temperatures are reviewed for trends, daily. However, the fridge and freezer alarms are not regularly tested (see shortfall against PFE2(e)) and are not serviced (see shortfall against PFE3(f)).

There are some samples being stored by the laboratory that are for return to relatives according to their wishes stated on the tissue forms sent by the Coroner’s Offices. However, despite numerous attempts to establish information to carry out these instructions, the laboratory has been unable to do so (see *Advice*, item 49).

Audits were conducted of three specimens selected at random; details were taken from the electronic database and compared with the tissue forms returned from the Coroner. Two of the specimens were for disposal; the date and method of disposal was recorded in both cases. The third sample had consent for research and was stored in the freezer. Samples within the freezer are bagged separately (by their unique case number), then kept in larger bags with numerous other samples, corresponding to the year the sample was taken. Therefore, the final audit could not be completed during the HTA inspection due to the time it would take to locate the specimens. There is no systematic record of sample storage location within the freezer (see shortfall against T1(g)). The establishment is required to complete this audit and provide evidence to the HTA.

Material held for the police

Home Office PM examinations are not undertaken by the establishment. However, there are specimens stored in the histopathology and neuropathology laboratories that have been sent to the establishment for specialist examination and Home Office pathologists use the establishment to process their specimens.

Under section 39 of the HT Act 2004, 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 at the establishment 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.

Inspection findings

Although the HTA found the Licence Holder, the Designated Individual and the premises to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of significant concern. Advice and guidance was given to the DI to further improve practices following the last inspection in 2014. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below. Although the DI has been deemed to a be a suitable person to hold the role, the shortfalls identified demonstrate that the he has not ensured that there are suitable practices in place for the conduct of the licensed activities.

The HTA will monitor progress of these shortfalls through the Corrective and Preventative Action (CAPA) plan to be completed by the establishment.

In addition, the DI has appointed Persons Designated (PDs) in areas covered by the licence but has not informed the HTA. Standard condition 10 in Annex B of the HTA licence issued to the establishment states:
"The Designated Individual may not substitute or add a person or persons designated under section 17 (b) of the Act, without first notifying the HTA in writing of the name of the proposed substituted or added person or persons designated."
The establishment has also therefore been in breach of a condition of their licence.

Compliance with HTA standards

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.	i) The Post Mortem Consent Policy for Southmead Hospital is only in a draft version, indicating that such a policy did not exist until recently, therefore it is not yet available to hospital staff. ii) The 'Post Mortem Consent Policy and Procedure' for St Michael's Hospital refers to the 'Next of Kin' and who that may be, which is not in line with the requirements of the HT Act 2004. For consent to be appropriate and valid under the HT Act 2004, consent must be obtained in accordance with the 'hierarchy of qualifying relationships' (see *Advice*, item 1).	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	i) There is no formal training for clinicians or other staff in obtaining consent for adult consented post mortems. ii) Training in paediatric/perinatal PM consent seeking is not consistent or formally scheduled for refresher training (the last training session was in 2015). (see *Advice*, item 6). As a result, the consent standards C2(c) and (d) cannot be met.	**Major**
b) Records demonstrate up-to-date staff training	There are no records of attendees who attended the paediatric/perinatal PM consent training in 2015.	**Minor**

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	i) The tissue traceability audit identified a perinatal consent form indicating that a full PM examination and an external (non-invasive) examination were required. The form clearly stated only one option should have been selected. There was no supporting documentation with the consent form to confirm this had been followed up to check which type of examination was required, prior to the full PM examination taking place. The SOP 'St Michael's: PM Examination Procedure' (CP-MORT-SOP-10), section 'Checking PM Consent and Identity' should include the procedure for following up anomalies/ issues with PM consent forms when they are identified and how these are resolved. (see *Advice*, item 15) ii) There is no documented SOP for lone working at St Michael's Hospital mortuary. However, lone working is a frequent occurrence in the mortuaries at both sites.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Minuted departmental staff meetings do not occur in most areas under the licence. There are no formal meetings between the DI and the Persons Designated (PDs) in each area covered by the licence. Communication and contact between the DI and staff who work under the licence appeared inconsistent. As a result, the DI cannot assure himself that he has sufficient knowledge and oversight of the activities in those areas. In addition, information relating to HTA relevant activities is not consistently shared with staff. Some staff were unaware of the implementation of the HTA's new codes and standards in April this year.	**Minor**

GQ2 There is a documented system of audit

a) There is a documented schedule of audits	The majority of areas covered by the licence do not have a schedule of audits (including bodies and/or tissue) or the frequency of the audits is insufficient, for example: i) Staff at St Michael's Hospital and Southmead Hospital mortuaries do not perform any audits, including those in relation to bodies and/or tissues. ii) The toxicology laboratory undertakes an annual audit of post mortem specimen (see *Advice*, item 22). iv) The respiratory research laboratory does not perform any audits of tissue being used in clinical trials or being held under the licence. As a result the Governance and Quality standards GQ2 (b) and (c) cannot be adequately met in most areas.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Although some staff have been initially 'signed off' on completion of training (Southmead Hospital only), there are no on-going competency assessments for staff within St Michael's Hospital or Southmead Hospital mortuaries. This includes the member of hospital bank staff who works on-call and the DI who periodically undertakes activities within the mortuary at Southmead Hospital. Competency (and training) assessments should be regularly completed for all staff, particularly those that work in the mortuary infrequently.	**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	A number of areas under the licence have no risk assessments and those that do, do not cover the full range of licensed activities, including risks to the deceased, tissue or traceability. For example: i) there are no risk assessments for St Michael's Hospital mortuary. ii) there are some risk assessments(for example, lone working) for Southmead Hospital mortuary but the scope of these require expanding. iii) the Urological RTB has not prepared any risk assessments (see *Advice*, item 26)	**Major**
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	The risk assessments in place at Southmead Hospital do not always include all the risks to the deceased in order to help identify mitigating actions. For example: i) the security risk assessment (No.41, version 1) does not consider access to bodies and confidential information. ii) the mortuary equipment failure risk assessment (No.44, version 1) does not consider the risk of decomposition to bodies.	**Minor**

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	i) Bodies released from Southmead Hospital mortuary are released using only the full name and no other identifiers. The release form issued to the funeral directors from the hospital only stipulates that the name of the deceased is required for release. All other information on this form relates to the relatives of the deceased (see *Advice*, item 10) ii) Bodies are often released from St Michael's Hospital mortuary using only two identifiers (see *Advice*, item 11) iii) The Neuropathology laboratory SOP 'Receipt and Booking in New Specimens' (NP/LAB/SOP/001), states PM specimens will be accepted in to the laboratory using the last name of the deceased only. Three identifiers (one being unique) should be used to identify specimens accepted by the laboratory.	**Major**

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	i) There are numerous patches of exposed plaster and flaking paint in the post mortem room, body store and ancillary areas in St Michael's Hospital mortuary. ii) The whiteboards on the fridges in St Michael's mortuary are scratched and marked making it difficult to remove identifying information (information from one body that had been released was still readable), leading to confusion and potential traceability issues.	**Minor**
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	i) Although there is an intercom at each access door to St Michael's Hospital mortuary, there is not a camera or CCTV to visually verify who is requesting access. This increases the risk of the doors being opened to unauthorised people, potentially causing a security and/or safety issue for staff who regularly work alone. ii) There are no panic alarms installed within the mortuaries (personal or fixed), for staff to alert security (see *Advice*, item 38).	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	i) Southmead Hospital Mortuary: the alarm trigger points for the main fridges in the body store (-1°C and 15°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. Mortuary staff are also unsure of the time period that elapses before the alarm will trigger. ii) St Michael's Hospital Mortuary: the upper alarm trigger point for the main fridges in the body store (10°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. Mortuary staff are not aware of the lower trigger point and are unsure of the time scale before the alarm will trigger. (See *Advice*, item 39)	**Major**
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	i) The perinatal, POC fridges and the Nutwell refrigeration units in the mortuary at Southmead Hospital are not connected to an alarm system. ii) The fridge on the maternity unit at Southmead Hospital is not alarmed. iii) In all areas that were inspected, where fridges and freezers are alarmed, these are not regularly challenged (see *Advice*, item 40).	**Major**

f) Temperatures of fridges and freezers are monitored on a regular basis	i) There is an 'informal' daily check of the temperature displays of the main banks of fridges in the body store at Southmead Hospital. Temperature monitoring of the fridges and freezer within the body store should be consistently undertaken and recorded. In addition, the electronic temperature record is not reviewed for trends to help identify a potential fridge or freezer failure. ii) Manual temperature checks of the Nutwell refrigeration units at Southmead Hospital mortuary are undertaken and recorded Monday to Friday the majority of the time and not consistently checked on weekends; only occasionally if staff are called in for viewings.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system in the post mortem room at St Michael's mortuary has not been serviced or maintained. Staff are not aware if the ventilation is operating to the required standard.	**Major**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	i) The fridge and freezer units that store post mortem samples within the toxicology laboratory, are not serviced or maintained. ii) There were no service or maintenance records available for the fridge and freezer units at St Michael's Hospital mortuary.	**Major**

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C1(a)	The DI is advised to review the PM consent policies for both hospitals to ensure they reflect the HTA's 'Guiding Principles and the Fundamental Principle of Consent' Code of Practice (Code A),and are therefore in-line with the requirements of the HT Act.
2.	C1(a)	During the inspection, advice was given to the PD in the Toxicology Laboratory in relation to specimens with consent for use for a scheduled purpose (e.g. research) under the HT Act 2004 and the 'hierarchy of qualifying relationships'. This included being aware that the person specified on tissue forms received from Coroner's Offices may not be the correct person for the purposes of consent under the HT Act 2004; therefore, this would need clarifying if there was any doubt. The DI is advised to ensure all staff working under the licence are aware of the relevant consent requirements under the HT Act 2004.
3.	C1(b)	The DI is advised to formally document the procedure for obtaining consent for research (for each RTB), when patients do not consent for this during their clinical appointments. The SOP should include how this will be managed to ensure appropriate consent is in place prior to any samples being taken for research..
4.	C1(f)	Although the patient information leaflets for each RTB provide the contact details of the relevant department, this isn't specifically referenced in the section about withdrawing consent. At the next opportunity, the leaflets should be updated to make this important information clearer for patients.
5.	C1(g)	The DI has been requested to remove the HTA logo from the adult consented PM examination forms and replace it with the relevant hospital's name and logo.
6.	C2(a)	The DI is advised to consider the options to ensure staff are trained, and their competencies regularly assessed, in adult and paediatric/perinatal PM consent seeking.
7.	GQ1(a)	The Person Designated (PD) in the Urology RTB has sought help and advice from colleagues in BRASH when developing policies and procedures. However, the majority of the documents reviewed for the Urology RTB make reference to the Neuropathology department, including procedures and the member of staff who is PD there. The DI is advised to ensure that the documents for the Urological RTB are adapted for that tissue bank.
8.	GQ1(a)	The DI is advised to include the procedure for long-term storage of bodies within the relevant SOP for St Michael's Hospital mortuary. Staff are aware of the procedure but it is not formally documented. The HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released of further examined, or before, depending on the condition of the body.
9.	GQ1(a)	Where SOPs refer to 'identification checks' of bodies or tissue in all areas under the licence, the identifiers should be detailed. There should be a minimum of three, including one unique identifier.

10.	GQ1(a)	The standardised release form used by the mortuary at Southmead Hospital does not contain enough information to sufficiently confirm identification of the body on release. The DI is advised to amend this form to ensure three identifiers are provided by the funeral director, one being unique. For example, full name, date of birth and address of the deceased.
11.	GQ1(a)	A standardised release form should be considered for the release of bodies at St Michael's Hospital mortuary. Although mortuary staff ask for a release form from funeral directors (in addition to the green disposal form), bodies are often released using only two identifiers. Three identifiers are required (one unique). A key identifier for babies and fetuses is the mother's name, which isn't always provided on release.
12.	GQ1(a)	Copies of PM consent forms for adult and paediatric/perinatal cases are not kept centrally or electronically at St Michael's Hospital mortuary or histopathology. Paper copies are retained by the pathologist who undertakes the post mortem, who may not be based on site and may not return them in a timely manner. This is the only copy the establishment has and it may take some time for the forms to be returned to the laboratory for filing. The DI is advised to copy and scan the PM consent forms so the establishment has a copy of the consent form and the important information it contains .
13.	GQ1(a)	The DI is advised to include the mother's date of birth on the 'Perinatal Post Mortem Request Form' as this can be important identifier in these cases.
14.	GQ1(a)	The DI is advised to consider scanning the consent forms received in the RTBs as a more robust way of storing these. They are currently stored only in paper format.
15.	GQ1(a)	The SOP 'St Michael's: PM Examination Procedure' (CP-MORT-SOP-10), section 'Checking PM Consent and Identity' states the APT and pathologist check that all sections of the consent form have been completed and are correct. However, it is important that the staff checking the consent forms have a sound understanding of the forms to ensure they are completed correctly. In addition, where any issues have been identified and followed-up, documented evidence should be kept with the consent form to demonstrate how the issue was resolved, prior to any examination taking place.
16.	GQ1(d)	The author and authoriser of the Southmead Hospital mortuary SOPs are not always different. Mortuary staff should be involved in writing SOPs and the SOPs then verified by someone who is familiar with mortuary practice and procedures.
17.	GQ1(d)	The DI is advised to ensure SOPs in all areas covered by the licence are regularly reviewed and updated accordingly.
18.	GQ1(d)	Some of the mortuary SOPs for St Michael's Hospital are in different formats. The DI is advised to standardise the format for consistency and avoid confusion.
19.	GQ1(d)	The forms used in the mortuary at St Michael's Hospital are not subject to document control; for example, the 'Post Mortem Tissue' form and 'UHB Face Sheet Fetal and Perinatal Post Mortem' form. The DI is advised to ensure all mortuary documents are subject to the same document control to prevent unauthorised and 'out of date' copies being used.

20.	GQ1(g)	The DI is advised to remove those PDs no longer required on the licence and have relevant PDs register for the portal for the HTA website to enable them to report HTARIs. This is especially important in the absence of the DI, as all HTARIs must be reported to the HTA within five working days of discovery.
21.	GQ1(g)	The PD in the Urology RTB is advised to inform the DI when the bank is to begin storing relevant material so the DI is aware that this activity has started.
22.	GQ2(a)	The DI is advised to ensure the Urological RTB and the Respiratory research laboratory develop an audit schedule, including regular horizontal and vertical audits of processes and stored specimens.
23.	GQ2(c)	Staff at the Toxicology Laboratory currently undertake an annual audit in relation to tissue being held. The DI is advised to increase the frequency and type of audit (horizontal and vertical) to ensure staff are fully aware of what is being held, and why, and to enable timely disposal of tissue where consent has not been given for continued retention.
24.	GQ3(a)	Porters at both sites should receive annual refresher training in mortuary practices and procedures, which is recorded. This will ensure they are up-to-date and competent in the tasks they undertake.
25.	GQ5(a)	The DI is advised to assure himself that all staff working in areas covered by the licence are aware of HTA Reportable Incidents (HTARIs) and the reporting procedure.
26.	GQ6(a)	The DI is advised to ensure: i) all licensed activities in the mortuaries are risk assessed on a regular basis. Please see the HTA website for a link to the following document 'Regulation of the Post Mortem Sector 2014-16, What we have learned' (page 20) which provides helpful information in relation to risk assessments: ii) the other areas covered by the licence consider the broad risks to relevant material, such as: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • inappropriate disposal This list is not exhaustive. In all areas, risk assessments should be reviewed regularly and also after changes to key procedures. The DI is advised to ensure that staff have access to risk assessments and that familiarity with them is incorporated into the staff training programme. In addition, electronic risk assessment records (on Q-Pulse) should have the correct risk assessment document attached. For example, the neuropathology risk assessment record for 'Specimen Transport (NP/BTB/45) had the risk assessment for the '-80°C Specimen Storage' attached.
27.	T1(a)	At Southmead Hospital mortuary, it is routine practice that identification details of bodies within the freezer are written on the outside of body bags. Although this is not done in place of labelling the bodies, there is a potential risk that the identification details on the bag are used to release a body, rather than physically checking the identification on the body. The DI is advised to cease this practice.

28.	T1(a)	The DI is advised to ensure all perinatal and paediatric cases, admitted to the mortuary have identification physically attached to the body, rather than the blankets or shrouds. This will help provide assurance that the body has been correctly identified.
29.	T1(b)	Currently, bodies admitted to the mortuary at Southmead Hospital are written in to the mortuary register in date order and all subsequent paperwork is filed in that order, in monthly batches. The DI may wish to consider introducing the use of a sequential 'mortuary register' number, allocated to each body as they are entered in to the mortuary register. This number can be used as an additional identifier for bodies while in the care of the mortuary and help with traceability and filing of mortuary paperwork.
30.	T1(b)	The DI is advised to ensure that sufficient identifiers of bodies are used on the fridge door whiteboards. It was noted during the body audits that the last name may only be used. As a minimum, the full name should be used, or the mother's name for perinatal bodies. The mortuary register number (suggested above) could also be used as an additional traceable reference for bodies.
31.	T1(b)	The DI may wish to consider the use of a documented log or register of all bodies placed in to the fridges on the maternity units at each site in order to highlight to staff the presence of a body and as a reminder to ensure transfer to the mortuary happens in a timely manner.
32.	T1(c)	Where bodies are admitted to St Michael's Hospital mortuary from other hospital's, the DI is advised to ensure the mortuary staff record any additional identifying information from that hospital on the 'Body Record Sheet'. This will further strengthen traceability of bodies admitted to the mortuary.
33.	T1(d)	Bodies with same and similar names are indicated by a rectangular magnet placed next to the name on the fridge door at both mortuaries. There is an additional step of adding a sticker to the body shrouding at St Michael's mortuary as a visual cue when releasing the body. The DI is advised to begin this practice at Southmead Hospital mortuary and introduce highlighting bodies with same/similar names in the mortuary register at both mortuaries. This will further mitigate the risk of bodies with same/similar names being incorrectly released and provide consistent practice across both sites. In addition, the same/similar name procedure, including any further checks/information required in these cases, will need to be included in the admission and release of bodies SOPs.
34.	T1(g)	Although labelled, specimens stored in the toxicology freezers cannot be easily located. Therefore traceability and audits of specimens in storage is difficult. The DI is advised to implement a system that will allow specimens to be easily located and audited.
35.	T1(h)	Contracted funeral directors are used by some hospitals to transfer babies and fetuses to the mortuary at St Michael's Hospital for PM examination. In most cases, a tracking document is used to maintain traceability between the referring hospital and the mortuary. The DI is advised to ensure the tracking document is used in all such cases and the funeral director has prior knowledge and appropriate information of which baby or fetus they are collecting from the mortuary, to mitigate the risk of incorrect release of a body. This is especially important if there are two or more cases from the same hospital.
36.	T2(a)	The DI may wish to consider informing Coroner's and police forces that use the toxicology, histopathology and neuropathology laboratories for analysis of their specimens, that where relatives have stated tissue can be used for research or

		education, such purposes may not available as an option and the tissue will be sensitively disposed of.
37.	T2(a)	Specimens held under PACE in the neuropathology laboratory are followed up annually. The DI is advised to ensure this happens more frequently (for example, quarterly) and ensure all specimens held under PACE are followed up. This will help mitigate the risk of tissue being kept longer than necessary.
38.	PFE1(d)	The DI is advised to follow up the hospital security recommendations to install panic alarms in the mortuary at Southmead Hospital and consider options for St Michael's Hospital mortuary, to ensure staff safety, especially when lone working and during viewings.
39.	PFE2(a)	The DI is advised to ensure fridge temperatures in all areas are maintained between 4-6°C, with lower and upper triggers points of around 2°C and 7°C, respectively, with an appropriate time period before the alarm triggers. The optimal operating temperatures for mortuary freezers is -20°C, +/- 4 degrees; the trigger points and time periods for the freezer alarms should allow for this. It is also important that all staff are aware of what the fridge and freezer temperatures should be to recognise any potential equipment failures before they occur.
40.	PFE2(e)	The DI is advised to ensure that fridges and freezers in all areas are regularly tested to ensure alarms will trigger when temperatures deviate from the required ranges. In addition, the DI may wish to consider linking the Nutwell units at Southmead Hospital mortuary to the existing remote alarm system to ensure staff are alerted to any temperature deviations.
41.	PFE2(f)	The DI is advised to ensure staff in all areas consistently monitor and record fridge and freezer temperatures, reviewing them for trends. Where possible, electronic system records should be regularly reviewed, to identify any potential equipment failure before it occurs.
42.	PFE2(f)	The DI may wish to consider linking the fridge in the maternity unit at St Michael's Hospital to the remote alarm system. The alarm sounds locally but due to the location of the fridge, this may not always be heard by staff on the ward.
43.	PFE2(h)	In St Michael's Hospital mortuary, more than one baby or fetus can be stored on a single tray within the fridges and freezers. Although bodies are not placed together (spaces are left) the DI is advised to explore better ways of keeping bodies separated. For example, the use of containers that can be labelled. This will mitigate the risk of property being mixed and make body traceability more robust.
44.	PFE3(a)	Although used infrequently, the DI is advised to replace the wooden body measure used in the body store in the mortuary at St Michael's Hospital. Wood is porous and cannot be easily decontaminated.
45.	N/A	The DI may wish to consider reviewing the processes at St Michael's mortuary to make them more streamlined and user friendly for the mortuary staff. The current processes and systems are time consuming, involving duplication of information. This is particularly difficult to manage when staff are working alone and pressured.
46.	N/A	When mortuary staff release bodies that pose a potential infection risk, the DI is advised to ensure they do not inadvertantly disclose information about the infection status of a body.The route of infection transmission may be disclosed (i.e. inoculation or inhalation) to ensure the appropriate PPE is used but the type

		of the infection should not. Information about deceased patients should be treated in confidence.
47.	N/A	The DI may wish to consider turning off the Nutwell Units housed at Southmead Hospital when not in use. This will help prolong the life of these units.
48.	N/A	All staff working under the licence are advised to subscribe to the HTA monthly newsletter, via the HTA website, to keep abreast of relevant information for the areas they work in.
49.	N/A	<u>Toxicology Laboratory</u> *Specimens currently being stored* The HTA advises that individual Coroners are provided with a list of the specimens being held on their behalf stating they will be sensitively disposed of after an appropriate timescale if they don't respond with instructions or, confirm the inquest is complete and the specimens can be dealt with accordingly. This includes those specimens that were for return to relatives but this couldn't be facilitated due to difficulties in receiving help and information from the relevant Coroner's Offices. The majority of the specimens for return to relatives (all from 2012-2016) have been held for considerable time, with no enquiries from relatives. Any specimens that are currently being stored for the police or other reasons, e.g. for paternity testing, will require regular documented follow-up with the relevant party, before the disposal instructions for those specimens are carried out. The date, method and the person responsible for the disposal of the specimens should be recorded. *Going forward* The HTA advises the establishment to implement a system where individual Coroner's are regularly provided with details of the cases currently being held by the laboratory on their behalf (e.g. quarterly), to determine if inquests have been completed so that specimens can be dealt with efficiently, in accordance of the relatives' wishes. The establishment will need to communicate with the Coroner's that use the service to agree on the time limit specimens will be held for if information in relation to completion of inquests is not received. The HTA's guidance for toxicologists states that where specimens are for return to relatives, they should be sent back to the establishment that they were sent from, for the relatives wishes to be acted on. This will prevent the laboratory storing these specimens indefinitely. The DI is advised to maintain sufficient oversight of the Toxicology Laboratory and regularly liaise with the PD to be aware of any problems that may arise and how these can be resolved. This advice will also be shared with staff in the toxicology laboratory.
50.	N/A	<u>St Michael's Hospital Mortuary</u> The inspection team were informed that the specimens stored in the -80°C freezer are 'existing holdings' (that is, they are samples that were already being held for use for scheduled purposes when the Act came into force on 1

		September 2006). There are no easily accessible records of the freezer's contents. The HTA has requested the DI to audit the contents of the freezer to establish a full inventory of the: - Type/s and number/s of specimens being stored; - Dates when specimens were collected/obtained; - Purpose/s for which they are being stored; Blocks and slides relating to some of the PM tissue being stored in the freezer are being stored elsewhere. These also need to be audited, documenting the same details as above.

Concluding comments

There are a number of areas of practice that require improvement, including 13 major shortfalls and 5 minor shortfalls.

The inspection team identified issues with storage of material for longer than necessary in some areas, for which advice should have been sought from the HTA. The volume and range of activities covered by the PM licence has increased since it was first issued in 2007 and may be a factor in the DI's ability to sufficiently oversee all the licensed activities.

The staff who work within the areas covered by the licence appear enthusiastic and committed to the work they undertake, despite increased workloads and staffing pressures in some areas. Examples of good practice included:

- The use of the mortuary register location reference on all mortuary documentation at St Michael's Hospital mortuary;
- Colour coding of specimen containers in the Neuropathology PM tissue collection, to indicate the year the specimen was first obtained;
- The 'body checklist' form, used in the mortuary at Southmead Hospital, to ensure identification details and the condition of the body has been checked.

The HTA requires the Designated Individual 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.

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.

Report sent to DI for factual accuracy: 23/10/2017

Report returned from DI: 07/11/2017

Final report issued: 21/11/2017

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: 31/10/2018

Appendix 1: HTA licensing standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Standards that are not applicable have been excluded.

Consent

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.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

Guidance

Refresher training should be available (for example annually).

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

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. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

Guidance

SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.

Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

Guidance

For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.

However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

Guidance

These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

As a minimum, the schedule should include a range of vertical and horizontal audits

checking compliance with documented procedures, the completion of records and traceability.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

Guidance

Staff should be made aware of the outcomes of audits and where improvements have been identified.

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.

Guidance

Audits of stored tissue should include samples held under the authority of the police, where applicable.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.

APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

Assessment of competence should include the standard of APTs' reconstruction work.

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

Guidance: attendance by staff at training events should be recorded.

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.

GQ4 There is a systematic and planned approach to the management of records

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

Guidance

HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.

Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

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.

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

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.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary.

Guidance

The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

Guidance

Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.

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.

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

   i. material sent for analysis on or off-site, including confirmation of arrival

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

Guidance

Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.

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.

Guidance

Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment forthese cases.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

Guidance

Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation

to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.

Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Storage arrangements ensure the dignity of the deceased.

Guidance

Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

Guidance

Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

Guidance

There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.

Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.

Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.

d) Fridge and freezer units are in good working condition and well maintained.

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.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.

Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities

forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements

with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

Guidance

COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.

d) Staff have access to necessary PPE.

Guidance

Where face masks should be worn, they should be face fitted.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

Guidance

This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.

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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or 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 both the draft and final inspection report. You 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 desk-based or site-visit inspection.

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