

Post Mortem Inspection Interview questions

Interviewee's name:		Interviewee's job title:	
Interview start time:		Interview end time:	

Introductory comments	Findings
<p>Describe your role and responsibilities</p> <p>How long have you worked here?</p> <p>Who do you report to?</p>	

Questions arising during inspection	Findings

YYYY-MM-DD [Licensing number] [Establishment name] inspection notes Interview conducted by: [Name] [Job title]

Reference number: HTA-TEM-009 **Last reviewed on:** 19 May 2015
Version number: 15.0 **Next review due:** 19 May 2016

Standard to be met	Findings
Consent (C):	
<p>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice</p> <ul style="list-style-type: none"> • Is there a documented policy which governs consent for post-mortem examination and the retention of tissue? <ul style="list-style-type: none"> a) <i>Does this cover both adult and paediatric cases?</i> b) <i>Does this reflect current HTA guidance and the SANDs documents?</i> • Is there a documented SOP detailing the consent process? (separate ones for adult/ paed. cases?) <ul style="list-style-type: none"> a) <i>Describe the process for seeking consent for adult and paediatric post-mortems?</i> b) <i>How do you know who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination?</i> • How would you communicate any issues with consent with the mortuary or with the DI? <p>SUDI/ research removal</p> <ul style="list-style-type: none"> • Is SUDI removal carried out under pre- 	

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Standard to be met	Findings
<p>emptive coronial authority or is consent taken (assume coroner's officers would turn up during normal hours anyway)?</p> <ul style="list-style-type: none"> • Is there a PD overseeing SUDI cases / removal for research? <p>Coroner's officers</p> <ul style="list-style-type: none"> • How does the Coroner notify the establishment that their authority is given for a PM examination? • Are you family with the HT Act Consent requirements? <ul style="list-style-type: none"> a) <i>Qualifying relationship hierarchy?</i> b) <i>What do you do if there are no family or they are too distressed to decide?</i> c) <i>What information is provided to the family regarding disposal or retention of tissue samples?</i> d) <i>How do you notify the establishment of the family's wishes?</i> e) <i>How do you notify the establishment of the end of the Coroner's authority?</i> • Do staff contact you if family wishes are not known, or if a body has been stored for a long time? 	
<p>C2 Information about the consent process is provided and in a variety of formats</p> <ul style="list-style-type: none"> • What written information is provided about the consent process? 	

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<ul style="list-style-type: none"> a) <i>What is the process if a relative changed their mind and how are relatives informed of this?</i> b) <i>Is the process for withdrawing consent in the documentation given to the family, including deadline for withdrawal of consent and contact details?</i> c) <i>How and when are relatives given an opportunity to ask questions?</i> • What options are given to the consent giver for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use)? <ul style="list-style-type: none"> a) <i>What information is provided about the potential uses in order to ensure that informed consent is obtained?</i> • If English is not the consent givers first language, or they have a disability (deaf/ blind etc), what assistance is available to ensure they receive all the necessary information to make an informed decision? • For donation of tissue to research (living or deceased) are there selection or exclusion criteria? 	

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Standard to be met	Findings
<p>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent</p> <ul style="list-style-type: none"> • Which staff are involved in taking consent (adults/paed. PMs/ tissue for research)? • How are staff trained? <ol style="list-style-type: none"> a) <i>Is refresher training available (e.g. annually)?</i> b) <i>How is attendance at consent training documented?</i> c) <i>If untrained staff are involved in consent taking, are they are always accompanied by a trained individual?</i> 	
Governance and Quality Systems (GQS):	
<p>GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process</p> <ul style="list-style-type: none"> • Do you have documented policies and SOPs to cover all mortuary/laboratory procedures relevant to the licensed activity? • For post-mortem examinations, does the SOP include the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases? 	

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<p>a) <i>What is the process for preparing for a pm examination?</i></p> <p>b) <i>How are you advised of those deceased who are to have a coronial pm?</i></p> <p>c) <i>Does the pathologist always undertake an external examination and check the ID of the deceased before evisceration?</i></p> <p>d) <i>If not how does the pathologist assure himself that it is the right person?</i></p> <p>e) <i>What is your policy for retrieval of tissue or organs for research or transplantation, e.g. eyes or brains?</i></p> <p>f) <i>Are tissue retrievers unaccompanied out of hours? If so, how do you know that they have accessed the mortuary?</i></p> <ul style="list-style-type: none"> • Do you have an SOP for record keeping? <ul style="list-style-type: none"> a) <i>Does this include how to make corrections?</i> • Do you have an SOP for receipt and release of bodies (out of hours arrangements)? <ul style="list-style-type: none"> a) <i>What is your process for identifying the deceased that are awaiting repatriation before release?</i> b) <i>What is your same or similar name process? White board/fridge/body/register?</i> c) <i>What identifiers for identification are used on ID bands? (minimum 3)?</i> 	

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<p>d) <i>What do you do if the ID of deceased is wrong?</i></p> <p>e) <i>What paperwork do you require for the release of the deceased to funeral directors?</i></p> <p>f) <i>What do you do if the funeral director arrives with incorrect paperwork?</i></p> <p>g) <i>Is there out of hours release of the deceased? If so who oversees this?</i></p> <p>h) <i>What would you do if the wrong body was released?</i></p> <p>i) <i>What is your procedure for dealing with 'long stayers?'</i></p> <ul style="list-style-type: none"> • Is there an SOP for the transfer of the deceased and tissue (including blocks and slides) to other establishments or off site ensuring that tissue is handled in line with documented wishes of the relatives? <ul style="list-style-type: none"> a) <i>How are you made aware of families wishes?</i> b) <i>Is there a system of chasing coroner's office if no instructions received on closure of inquest / family wishes?</i> • Is there an SOP for the removal of tissues in SUDI cases or for research? <p>(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)</p> <ul style="list-style-type: none"> • How often are policies and procedures 	

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<p>reviewed (for example, every 1-3 years)?</p> <ul style="list-style-type: none"> • Is there a system for recording that staff have read and understood the latest versions of these documents? • What meetings take place that relate to licensed activities? <ul style="list-style-type: none"> a) <i>How often do they take place?</i> b) <i>Are they minuted?</i> c) <i>Who attends?</i> d) <i>Do you attend any meetings with PDs for maternity/ SUDI removal/research?</i> 	
<p>GQ2 There is a documented system of quality management and audit</p> <ul style="list-style-type: none"> • Describe your system of version control of Policies and SOPs (ensure only the latest versions available for use). • How are deviations from documented SOPs recorded and monitored? • Describe what audits are carried out (vertical and/or horizontal audits), for example: <ul style="list-style-type: none"> ○ <i>Horizontal Audit against HTA standards</i> ○ <i>Receipt/release of deceased.</i> ○ <i>Identification of the deceased</i> ○ <i>Documentation of consented hospital PM examinations</i> ○ <i>Traceability of tissue from PM room</i> 	

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Standard to be met	Findings
<ul style="list-style-type: none"> ○ <i>Witness/Observational audits of staff carrying our procedures,</i> ○ <i>Audits of 'long stayers'</i> • Describe what the audits review e.g. compliance with documented procedures, records (for completeness) and traceability. • What is the process for dealing with audit findings? <ul style="list-style-type: none"> a) <i>Process for reporting/monitoring actions?</i> b) <i>Timeframes?</i> c) <i>Do you inform DI and if so how?</i> d) <i>If you don't how are major findings addressed?</i> e) <i>Is there an SOP?</i> • Are there regular audits of tissue being stored at the establishment that ensure that staff are fully aware what material is held and why? <ul style="list-style-type: none"> a) <i>Are they being held in line with families wishes?</i> b) <i>Whose authority are they being stored under?</i> c) <i>How are they reviewed to ensure the appropriateness of their continued retention</i> d) <i>Where relevant, what processes are there in relation to police holdings?</i> • Is there a complaints system in place? 	

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Standard to be met	Findings
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</p> <ul style="list-style-type: none"> • Are staff appropriately trained/qualified or supervised? <ul style="list-style-type: none"> a) <i>What qualifications do mortuary staff hold? (New Qualifications in place for AAPT's)</i> b) <i>Who does SUDI removal and what qualifications/ training do they have?</i> c) <i>Who does removal for research and what qualifications/ training do they have?</i> • Do staff have annual appraisals? • Are staff given opportunities to attend training courses, either internally or externally? (give examples) • How is attendance by staff at training events recorded? • Is there a documented training programme for new staff (e.g. competency checklist)? <ul style="list-style-type: none"> a) <i>Trust induction and local induction for new starters?</i> b) <i>Also, for visiting / trainee pathologists?</i> c) <i>Is there any specific training for portering staff on the activities in the mortuary? (e.g. receipt of a body, equipment, HTARIs)</i> 	

HTA-TEM-009-15.0 [Licensing number] [Establishment name] inspection notes Interview conducted by: [Name] [Job title]

Reference number: HTA-TEM-009 Last reviewed on: 19 May 2015
Version number: 15.0 Next review due: 19 May 2016

Standard to be met	Findings
<p>GQ4 There is a systematic and planned approach to the management of records</p> <ul style="list-style-type: none"> • Is there a system for managing records which includes: <ul style="list-style-type: none"> a) <i>which records must be maintained?</i> b) <i>how they are backed up?</i> c) <i>where are records kept?</i> d) <i>how long each type of record is retained?</i> e) <i>who has access to each type of record?</i> <p>(Things you'd expect to be covered: Mortuary Register with receipt and collection, PM details recorded, Tissue traceability)</p> <ul style="list-style-type: none"> • Is there a Computer backup system of all details for traceability of deceased, tissue, valuables? • Is there a documented SOP for record management? 	

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Standard to be met	Findings
<p>GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</p> <ul style="list-style-type: none"> • How are the deceased tagged/ labelled upon arrival at the mortuary? • <i>How are unidentified bodies labelled?</i> • Which identifiers are used to identify the deceased prior to PM or release? • How are details of organs retained and the number of wax blocks and tissue slides recorded? • <i>How are samples sent between establishments traced?</i> • <i>How are details recorded of tissue that is repatriated or released with the body for burial or cremation?</i> • Are audits of tissue storage and traceability undertaken to ensure compliance with operational procedures and how often? • <i>What happens to tissue samples found which are not being stored with consent (disposed of with reference to the family's wishes)?</i> <p>SUDI/ research removal</p> <ul style="list-style-type: none"> • What samples are taken (e.g. is there a standard list of these)? <ul style="list-style-type: none"> a) <i>Where do the samples go?</i> b) <i>Who does this sampling?</i> 	

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Standard to be met	Findings
<p>GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly</p> <ul style="list-style-type: none"> • Are staff trained in how to use the incident reporting system? • How do you know which incidents and near-misses must be reported, including those that must be reported to the HTA? <ul style="list-style-type: none"> a) <i>Who is responsible for reporting, investigating and follow up for incidents?</i> b) <i>How do you ensure those investigating serious incidents are competent to undertake root cause analyses?</i> c) <i>How do you ensure that follow up actions are identified (i.e. corrective and preventative actions) and completed?</i> • How is information about incidents shared with all staff (including the reporter) to avoid repeat errors? • What is the process for communicating with families where necessary? 	

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Standard to be met	Findings
<p>GQ8 Risk assessments of the establishments practices and processes are completed regularly and are recorded and monitored appropriately</p> <ul style="list-style-type: none"> • Are all procedures related to the licensed activities (as outlined in standard GQ1) risk assessed? <ul style="list-style-type: none"> a) <i>Who is involved in conducting risk assessments, have they received training in this?</i> b) <i>Do all staff undertaking licensed activities have access to the risk assessments?</i> c) <i>Do risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks?</i> d) <i>Are risk assessments aimed at protecting the deceased?</i> e) <i>Do risk assessments include how to mitigate the identified risks (actions that need to be taken, who is responsible, deadlines for completing actions and confirmation when completed)?</i> • How often are risk assessments reviewed (along with SOPs, for example every 1-3 years?) 	

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Version number: 15.0 Next review due: 19 May 2016

Standard to be met	Findings
Premises, facilities and equipment (PFE):	
<p>PFE1 The premises are fit for purpose</p> <ul style="list-style-type: none"> • Is there sufficient space for the activities to be carried out? <ul style="list-style-type: none"> a) <i>Receipt and release areas?</i> b) <i>Storage – enough fridges and freezers, bariatric facilities, baby fridge?</i> c) <i>PM examination room?</i> d) <i>What are your contingency arrangements and have you ever used them?</i> • Are any surfaces made of non-porous materials? <ul style="list-style-type: none"> a) <i>Are surfaces easy to keep clean – how do you clean them- with what, how often, recorded?</i> • Are you aware of any issues with the condition, structure or cleanliness of the premises? • Are you assured that the premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records)? <ul style="list-style-type: none"> a) <i>How is access gained to the mortuary for staff, Visitors, Funeral Directors?</i> b) <i>What security systems are in place?</i> c) <i>Who and how are premises accessed out of hours?</i> d) <i>Is there a record of Visitors in the</i> 	

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Standard to be met	Findings
<p><i>mortuary?</i></p> <p>e) <i>Is there controlled access to the deceased?</i></p> <p>f) <i>Separate locked areas – office, PM room?</i></p> <ul style="list-style-type: none"> • Where does SUDI removal take place? <ul style="list-style-type: none"> a) <i>How is the dignity of the deceased maintained?</i> b) <i>How is the security and cleanliness of the area maintained?</i> • Where does removal for research take place? <ul style="list-style-type: none"> a) <i>How is the dignity of the deceased maintained?</i> b) <i>How is the security and cleanliness of the area maintained?</i> 	

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<p>PFE 2 Environmental controls are in place to avoid potential contamination</p> <ul style="list-style-type: none"> • Is appropriate PPE available and routinely worn by staff? Describe the PPE. • What critical equipment and/or PPE is available for high risk post mortems? a) <i>What is the procedure for high risk PMs? i.e. done last and with minimal members of staff</i> • Describe the cleaning regimen and the frequency each area is cleaned. • Are there documented cleaning and decontamination procedures? 	
<p>PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.</p> <ul style="list-style-type: none"> • Where are deceased or tissue samples stored under licence? <ul style="list-style-type: none"> ○ <i>Adults/ Paediatric deceased</i> ○ <i>Pregnancy remains</i> ○ <i>SUDI samples</i> ○ <i>Forensic samples</i> ○ <i>Toxicology samples</i> ○ <i>Wet tissues/ blocks/ slides</i> • Are refrigerated storage units in good working condition and well 	

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<p>maintained?</p> <p>a) <i>Are they maintained – How often, By whom, Is it recorded?</i></p> <p>b) <i>Temperature Controlled – How often checked?</i></p> <p>c) <i>How are temperatures recorded and what is the normal range?</i></p> <p>d) <i>What are the trigger points for the fridge/ freezer alarm system?</i></p> <p>e) <i>How often do you test the alarm system?</i></p> <p>f) <i>How do you report an equipment fault?</i></p> <p>g) <i>Do you have freezer storage and how often is it used?</i></p> <ul style="list-style-type: none"> • Are there contingency plans in place should there be a power failure, or overflow? <ul style="list-style-type: none"> a) <i>Are the contingency plans documented?</i> b) <i>Do they have SLAs in place?</i> • Are there temporary storage units and are these alarmed/ checked? • Is there separate storage for infants and babies in the mortuary, or other areas of the hospital? <ul style="list-style-type: none"> a) <i>Are these alarmed?</i> b) <i>If no separate storage are special measures taken for the bodies of infants and babies?</i> 	

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<p>PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination</p> <ul style="list-style-type: none"> • Are bodies, body parts or tissues transported to another establishment, if so where? <ul style="list-style-type: none"> a) <i>What is the procedure for transporting bodies, body parts or tissues?</i> b) <i>How do you ensure these have reached their destination?</i> c) <i>Do they get returned?</i> d) <i>Are there documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements?</i> • Are there written agreements in place with any external parties (e.g. undertaker, or courier) who transport the deceased and/or tissue on behalf of the establishment (laboratory or mortuary)? <p>(Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases)</p>	

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<p>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored</p> <ul style="list-style-type: none"> • Are all Items of equipment in the mortuary in a good working condition and appropriate for use? <ul style="list-style-type: none"> ○ fridges / Freezers ○ hydraulic trolleys ○ post mortem tables ○ hoists ○ saws (manual and/or oscillating) ○ PPE for high risk cases (e.g. respirators) • Is any of the equipment made from porous materials? Has this been risk assessed? i.e Wooden measuring sticks or wooden handled chisels • Do you keep the maintenance/ service records for equipment, including fridges/freezers, trolleys, post mortem tables (if draught) and post mortem suite ventilation? <ul style="list-style-type: none"> a) <i>If not, do you get notified by estates when equipment has been maintained or the cause of any fault, so that you can continue to monitor the equipment?</i> <p>(Note that these records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)</p>	

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Version number: 15.0 Next review due: 19 May 2016

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Disposal (D):	
<p>D1 There is a clear and sensitive policy for disposing of human organs and tissue</p> <ul style="list-style-type: none"> • Is there a documented Trust or mortuary/ laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal? <ul style="list-style-type: none"> a) <i>Do you have defined timeframes for tissue disposal?</i> b) <i>Where is tissue sent for sensitive disposal? Do you have an SLA in place with them?</i> c) <i>How are you informed of whether tissue should be disposed of?</i> d) <i>What is your policy if the family do not provide their wishes with respect to disposal?</i> • What are the disposal arrangements for pregnancy remains? <ul style="list-style-type: none"> a) <i>Are you familiar with the HTA guidance?</i> 	

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<p>D2 Post Mortem tissue is disposed of if consent is not given for its storage and use for scheduled purposes</p> <ul style="list-style-type: none"> • Describe how whole organs, wet tissue, wax blocks and microscope slides are disposed of. <i>a) What details of disposal of organs and tissue blocks are recorded? And where?</i> • How do you ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family? • How do you ensure that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death? (rolling programme) 	

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Concluding comments	Findings
<p>Any questions from interviewee?</p> <p>Do you have any concerns about anything relating to the HTA licence?</p> <p>Any areas of good practice that you are proud of?</p> <p>Any areas where you know there is room for improvement?</p>	

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