

Site visit inspection report on compliance with HTA minimum standards

Frimley Park Hospital

HTA licensing number 30014

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**

10 November 2015

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Frimley Park Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to consent and governance and quality systems.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

Frimley Park Hospital (the establishment) is one of four hospitals, which together form the Surrey Pathology Services (SPS) network. The establishment carries out approximately 180 PM examinations each year on behalf of HM Coroner for Surrey and a small number of hospital consented PM examinations. It does not perform any forensic or high risk PM examinations. High risk PM examinations are referred to another HTA licensed establishment, as are perinatal and paediatric cases. Consent for these is taken by clinicians in the hospital. Outside the mortuary, there are no activities taking place under this HTA licence.

Occasionally, NHSBT tissue retrieval teams attend to undertake tissue removal for use in patient treatment. This activity is covered by NHSBT's HTA licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Tissue samples taken during PM examination are processed in the Histology Department and sent for analysis to the Royal Surrey Hospital, also part of the SPS network, where they are either stored or disposed of in line with the wishes of the family.

The establishment is staffed by a senior Anatomical Pathology Technologist (APT), a trainee APT and a contracted locum Mortuary Assistant. The Mortuary Services Manager oversees mortuary activity and an Associate Practitioner of Histology is responsible for ensuring traceability of tissues and appropriate disposal in line with the wishes of the family. The Designated Individual is a Consultant Histopathologist based in the Hospital and has regular meetings with staff involved in HTA-licensed activities.

The mortuary has 60 fridge spaces. Five of these spaces can be converted to freezers if required. There is space for bariatric bodies and a dedicated space for the storage of babies (see advice item 7).

The PM suite has three designated workstations, each with a set of height-adjustable stands that hold the mortuary trays on which the PM examinations are performed. Each workstation has a down-draft dissection bench. Air flow in the PM suite is serviced regularly and servicing records were up to date. At the time of inspection, the PM suite was not in use due to maintenance work being carried out and PM examinations were being referred to another hospital within the SPS network. The establishment reported this to the HTA prior to the inspection.

Audit trails were conducted on two adult bodies and one baby stored in the refrigerators, two of which included similar last names. Body location and identification details on wrist tags of the bodies were cross referenced against the information on the whiteboard, paper mortuary registers and computer records. No anomalies were found in two of the cases. In one case, the person who had given consent for the PM examination had previously declined the request and then changed their mind, but this was not recorded in the mortuary case notes (see minor shortfall GQ4 and advice item 5).

An audit trail was also conducted on a hospital consented PM and a Coroner's case. In both cases, histology was taken and then sent to Royal Surrey Hospital for analysis. In the hospital consented case, the consent form did not state the relationship with the deceased of the person who had given consent (see minor shortfall C1 and advice item 1).

This was the third routine site visit inspection of the establishment since it was issued an HTA licence in 2007 (the last inspection having taken place in 2013). All shortfalls from the previous inspection had been addressed prior to this inspection and evidence was reviewed during this inspection, which included a visual inspection of the mortuary, PM suite, body store, viewing room and Histology. Interviews with members of staff and a review of documentation were undertaken. In addition, discussions with bereavement midwives took place to inform the inspection findings with regard to PM examinations of infants.

Inspection findings

The HTA found the Designated Individual and the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

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 code of practice	<p>During the traceability audit, a hospital PM consent form was found to have been completed incorrectly in that it did not record the relationship between the person who gave consent and the deceased.</p> <p>Although the DI had sought confirmation that the person who had given consent was the appropriate person, in line with the qualifying relationships described in the Human Tissue Act 2004 (the HT Act), the consent form had not been updated to reflect this (see advice item 1).</p> <p>Seeking consent for hospital PM examination is governed by a documented procedure and associated guidance. The traceability audit undertaken by the HTA demonstrated that not all clinicians are following the procedure, which increases the risk of activity taking place without appropriate consent.</p>	Minor

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records	<p>During the traceability audit, records for consented PM examinations were reviewed. In one of the cases, the family had initially declined the request for a PM examination but later changed their minds and a PM examination was conducted. This information had been communicated verbally to the mortuary by bereavement staff; however appropriate paper records were not updated (see advice item 5).</p>	Minor

Advice

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

No.	Standard	Advice
1.	C1/C3	The establishment has developed a consent training booklet for staff seeking consent for hospital consented PM examinations. The DI is advised to make sure that staff seeking consent are also aware of the documented consent

		procedures. In addition, the HTA advises that staff trained in seeking consent sign to confirm that they have read and understood the consent training booklet and associated procedures. This will help ensure that consent forms are completed properly and that consent is obtained in line with the requirements of the HT Act 2004.
2.	GQ1	On occasion, viewings take place out of hours with porters and hospital site managers who have received formal training by an APT beforehand. However, these viewings are not always recorded in the viewing log. The DI is advised to make sure that relevant hospital staff are aware of procedures governing viewings to ensure that a record is kept of all the visitors in and out of the mortuary.
3.	GQ2	Audits of licensable activities are carried out regularly by staff. The establishment is advised to formalise the audit schedule as to which audits of licensable activities will take place within a certain timeframe.
4.	GQ3	The Senior APT will soon be taking a period of extended leave. The DI should consider having someone in place before they leave, so there is a formal handover and to ensure that the new staff member is familiar with routine mortuary procedures.
5.	GQ4	Where families change their mind regarding consent for a PM examination, the records of communication and relevant paperwork should be kept in the mortuary to ensure that they have the most up to date information about each case.
6.	GQ7	The DI is advised to ensure that staff routinely use the Trust's incident reporting system to report all mortuary-related incidents. The DI may wish to use this incident log for shared learning with staff to mitigate the risk of repeat incidents.
7.	PFE3	The DI is advised to label the paediatric fridges/shelves in the mortuary. This will give mortuary staff and porters a visual reminder of where to put paediatric bodies and reduce the risk of the body of a baby being misplaced.
8.	PFE5	The mortuary was clean and cleaning takes place on a regular basis. The DI is advised to introduce a system of recording cleaning to show the cleaning routine.
9.	PFE5	The DI is advised to review fridge temperature records for trend analysis. This will give staff an indication if the current temperature is approaching a level at which action may need to be taken.
10.	N/A	The mortuary is currently holding samples from coronial PM examinations for use for research, where the family has indicated that this is what they would like done with the samples. However, the material may not be used. The DI should consider developing a policy on the retention and disposal of material donated for research and liaising with the coroner, requesting that families are made aware that the samples may be disposed of.

Concluding comments

Despite the shortfalls, many areas of good practice were observed throughout the inspection:

- The establishment has a robust identification procedure for cross checking paperwork of bodies brought into the mortuary, which highlight any transcription errors in the paperwork.
- There is good verbal communication between mortuary and bereavement staff in the Maternity Department.
- There are thorough risk assessments of licensable activities in the mortuary.

The HTA has given advice to the Designated Individual on a range of issues including consent, governance and quality systems and mortuary practices.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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 November 2015

Report returned from DI: 7 December 2015

Final report issued: 7 December 2015

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: 9 December 2015

Appendix 1: HTA standards

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

Consent standards
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
<ul style="list-style-type: none">• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.• There is a documented SOP detailing the consent process (including 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).• There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is made clear who should be contacted in this event.• Information contains clear guidance on options 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).• Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.• Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
<ul style="list-style-type: none">• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.• Refresher training is available (e.g. annually).• Attendance at consent training is documented.• If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
 - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
 - record keeping
 - receipt and release of bodies, which reflect out of hours arrangements
 - lone working in the mortuary
 - transfer of bodies 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
 - disposal of tissue (including blocks and slides)
- (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)*
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
 - There is a system for recording that staff have read and understood the latest versions of these documents.
 - Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

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

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

(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.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
 - fridges / Freezers
 - hydraulic trolleys
 - post mortem tables
 - hoists
 - saws (manual and/or oscillating)
 - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if draught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures 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.

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.