Site visit inspection report on compliance with HTA minimum standards

Gravelly Park

HTA licensing number 12347

Licensed under the Human Tissue Act 2004 for the storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose

2 May 2012

Summary of inspection findings

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

Although the HTA found that Gravelly Park (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to systems for establishing traceability.

The establishment is an archive for evidential material arising from criminal investigations, including tissue samples, formerly held at various licensed establishments which formed part of Forensic Science Services Limited ("FSS"). Its first priority has been to integrate the different systems previously used to catalogue and trace material and produce a full inventory of its holdings.

The DI has recently been appointed in light of their background in logistics and materials tracking, and is overseeing the creation and management of the systems used for this purpose. The shortfall reflects that systems have not yet been finalised and therefore an inventory of materials has not yet been completed.

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 Paragraph 18 of the Human Tissue Act 2004 ("the Act"). 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

The establishment, together with its satellite premises**,** is an archive facility holding tissue and other samples arising from criminal investigations, including those removed during coronial post mortem examinations previously carried out by the FSS, which has ceased to operate. Tissues held elsewhere within FSS have been transferred to the establishment for ongoing storage.

Most of the material held by the establishment does not fall under the auspices of the Act; much of it is not relevant material and where relevant material is stored, the majority was retained under the Police and Criminal Evidence Act 1984 (PACE). However, there are circumstances where a criminal investigation has been closed but the Coroner's investigation into the cause of death continues. In those circumstances, the tissue held would fall within the remit of the Human Tissue Authority.

As the FSS has ceased to operate, no further tissue samples will be transferred to the establishment. The establishment is thus operating purely as an archive facility and staff are presently undertaking an inventory of holdings, cataloguing all items, including evidence material, tissue samples and related case files and documentation, in order to enable materials required in ongoing court cases to be retrieved.

The inventory is also intended to ensure that all material is held in archive for the appropriate time scale, dependant on the nature of the crime to which it relates. As a by-product of this, any tissue not held under PACE, and thus falling within the remit of the HTA, will be identified.

When the post mortem facility of FSS ceased to operate, staff there reviewed all tissue samples held in advance of their transfer to the establishment, seeking instructions from the relevant coroners as to their disposal. Tissue samples were either returned to the families of the deceased or disposed of on the coroner's authority, according to instructions received.

Any remaining tissue samples, only being wax blocks and slides, were then transferred to the establishment's satellite site with related spreadsheets, paper files and documentation. The information from these spreadsheets has not yet been transferred to the establishment's database but on the day of inspection a former member of staff of FSS was assisting establishment staff in analysing the spreadsheets in preparation for data transfer.

During the planned inventory process, which is estimated to take twelve months, for each item held staff will identify whether it falls under PACE or under the authority of a coroner. In the latter case, a further check will be made to determine whether the coroner's authority has ended. When that has been clarified, the material will then be dealt with in accordance with any instructions provided by the coroner, i.e. disposed of, returned to the family or transferred elsewhere for use for research or other scheduled purposes. Importantly, the intention is that the establishment will eventually not hold any material falling under the remit of the Act.

The quality management system has been adapted from the previously existing FSS system, but has not yet been rolled out to staff. Various elements of the governance and facilities management are in the course of being handed over or adapted and the procedures relating to the inventory and cataloguing exercise are in the course of being drafted.

The inspection had been scheduled following notification to the HTA of the planned closure of FSS. It was also an opportunity for the HTA to provide advice to the archive staff on how any stored tissues and cells identified as falling within the remit of the HTA should be dealt with following the inventory.

The inspection comprised a visual inspection of the premises, interviews with archive staff and a review of documentation, including the quality manual, relevant standard operating procedures, maintenance and calibration records for the cold store facilities, training records and the report of a recent BSI ISO 9001 audit.

The HTA also had the opportunity to discuss the procedures relating to the transfer of tissue samples from the FSS post mortem facility with a former member of staff, who had attended the establishment on the day of the inspection to instruct staff on the interpretation of the related spreadsheets.

The standards applicable to disposal were not assessed on the day of inspection as the establishment is not yet disposing of tissues held. Policies and procedures are being drafted and advice has been provided by the HTA in that regard.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	At the time of inspection, a full inventory of those samples received from the former post mortem facility of FSS had not been carried out and relevant documentary information not yet uploaded to the overarching database. Accordingly, traceability of each tissue sample stored under the HTA licence could not be fully demonstrated. While this means that this standard is not met, the HTA recognises that in advance of transfer of tissue samples from the post mortem facility of FSS (these samples being the most likely to fall within the remit of the HTA) an inventory had been carried out and, where possible, tissues disposed of in accordance with instructions received from the coroners involved. It also recognises that the likelihood of any other tissues falling under its remit being held is extremely small. Further, the HTA recognises that the DI has been engaged primarily in order to manage the complete cataloguing of tissues, other samples and documentation held within the archive and that in due course any tissues falling outwith PACE will be dealt with in accordance with instructions received from the relevant coroners. As the establishment is not accepting any further tissues into archive, the eventual result will be that it only holds tissues obtained under PACE and will therefore not require to be licensed by the HTA. Taking all these circumstances into account, the HTA has taken the proportionate view that the shortfall may be considered minor. (see Appendix 2)	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to finalise policies and procedures in relation to disposal of tissues and cells in accordance with HTA Codes of Practice and to ensure that staff are trained on same, with training being recorded.
2.	GQ1	The DI is advised to ensure that reminder systems are set up to provide for regular review of the policies and SOPs which have been drafted or amended from the previous FSS versions, particularly in the early stages of activity while systems are being refined.
3.	PFE5	The DI is advised to ensure continuity in the arrangements made for maintenance, validation and calibration of the freezers used for storage of archive material following termination of any former contractual arrangements with FSS.
4.	D!/D2	The DI is advised to seek guidance from the HTA following the completion of the inventory of the archive on how any tissues falling within the remit of the HTA are dealt with, to ensure compliance with HTA Codes of Practice, and the relevant legislation.
5.	N/A	The DI is advised to ensure that, on any change to the identity of the corporate entity responsible for holding an HTA licence, the HTA is advised to that the necessary licence variation may be made.

Concluding comments

The establishment has taken the decision to completely catalogue all materials it holds. Despite only being in existence as a separate entity for a comparatively short time, good progress has been made in developing an overarching database to collate information held in various other databases as the first step in the process of determining the provenance of all tissues and other samples held in archive.

Much work has been carried out in adapting the existing FSS governance documentation to meet the needs of an establishment which only carries out archive storage.

The DI is keen to take advice from the HTA on how tissues should be dealt with following the completion of the inventory, in order to ensure compliance with relevant legislation, standards and codes of practice, with the ultimate aim of the archive no longer retaining any tissue held other than under PACE.

Staff are obviously aware of the licensing position with regard to tissues not held under PACE and are developing the processes to be followed when cataloguing and tracing materials held. A logical, methodical plan of action has been developed to ensure that there is best possible accuracy in logging materials stored in order that the DI will be confident regarding the origin and provenance of any tissue samples held.

The storage facility is covered by good security measures, and staff employed at all levels have been subject to comprehensive background and CRB checks and are subject to strict regulation regarding confidentiality. The facilities are well maintained, with cold storage units being subject to regular preventative maintenance, calibration and monitoring.

The archive has yet to be fully inventoried and this has been reflected by the HTA recording one minor shortfall. The HTA has given advice to the Designated Individual with respect to finalisation of governance arrangements following the change from FSS to the current arrangements.

The HTA requires that the Designated Individual addresses the shortfall 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 18 May 2012

Report returned from DI: 14 June 2012

Final report issued: 18 June 2012

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: 13 August 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
C2 Information about the consent process is provided and in a variety of formats
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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 downdraught) 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. • There are documented procedures for disposal of human tissue, including blocks and slides.
D2 The reason for disposal and the methods used are carefully documented
• There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family. • Disposal records include the date, method and reason for disposal. • Tissue is disposed of in a timely fashion. *(Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)*

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.