Site visit inspection report on compliance with HTA minimum standards

School of Biomedical Sciences, Nottingham

HTA licensing number 12085

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen.**

17 to 19 September 2013

Summary of inspection findings

Although the HTA found that The School of Biomedical Sciences, Nottingham (the establishment) had met the majority of the HTA standards, a major shortfall was identified in relation to the storage of bodies that are frozen rather than embalmed. The current arrangement for the storage of frozen bodies does not meet HTA standards as, unlike the arrangements for the storage of embalmed bodies, it does not preserve the dignity of the deceased during storage or during the movement of bodies prior to, and after, their use in surgical training courses.

In addition to the major shortfall, which is reported under standard PFE3, advice and guidance is provided in a number of areas where the HTA identified opportunities for improving existing systems and procedures.

Examples of a number of strengths and 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

The establishment comprises a hub facility at The School of Life Sciences, Nottingham and two satellite facilities at:

- The School of Graduate Entry Medicine and Health Studies, The Royal Derby Hospital, Derby; and
- The School of Veterinary Medicine and Science, University of Nottingham, Sutton Bonington Campus, Leicestershire.

The School of Life Sciences (until recently known as: 'The School of Biomedical Sciences') is a major undergraduate teaching resource within the faculty of Medicine and Health Sciences at the University of Nottingham. The establishment also provides postgraduate training facilities for the teaching and education of medical professionals. Approximately 250 medical students undergo training involving anatomical examination throughout the first and second years of the Bachelor of Medicine degrees. The premises are also used for teaching approximately 50 students per year on the Neuroscience Bachelor of Science degree course and for teaching approximately 55 trainee physiotherapists. Postgraduate training includes masters' degrees in Sports Medicine and Nursing and surgical training courses associated with the adjacent Queen's Medical Centre. Donors are accepted into the bequeathal process provided they match established acceptance criteria. This includes obtaining consent in accordance with HTA's consent standards. Once accepted into the establishment, the majority of donated bodies are embalmed prior to use. A proportion of donated bodies are selected for use in the specialist surgical training courses run in conjunction with Queen's Medical Centre. These bodies are frozen, rather than embalmed.

The School of Graduate Entry Medicine and Health Studies at The Royal Derby Hospital offers graduates from other disciplines the opportunity to take a Bachelor of Medicine course over four years rather than five. Midway through their second year, students merge with students on the University of Nottingham medical degree course. The School of Life Sciences has short term and long term loan arrangements for the provision of prosected specimens to the satellite premises at Derby for the purpose of scheduled modules of teaching and demonstration. Students on the course at Derby do not carry out anatomical dissection. The facilities are also used to teach students undertaking a Bachelor of Science degree in Medical Physiology and Therapeutics. The premises at Derby have also been used for surgical training courses using fresh frozen tissue, imported from the USA.

The School of Veterinary Medicine and Science, Sutton Bonington Campus is the University of Nottingham's teaching facility for veterinary students. The School of Life Sciences has short term loan arrangements for the provision of prosected specimens to the satellite premises at Sutton Bonington for scheduled sessions of comparative anatomy and physiology associated with the veterinary medical science degree course.

The licensed premises at the School of Life Sciences, Nottingham, comprise a body store / mortuary, an embalming / preparation area, a dissection room, four teaching, 'task', rooms and an office area. Donor bodies are used for the purpose of anatomical examination at the medical school and used to educate and train medical and allied health care students.

This is the second site visit inspection of the establishment by the HTA. The first inspection took place in July 2006 when the HTA undertook a pilot site visit. The timetable for inspection was developed following pre-inspection discussions with the Designated Individual (DI) and with due consideration of the results of the initial site visit and desk-based assessments at the time of initial HTA licence application and the June 2011 self-assessment requested of the

anatomy sector under HTA Directions 002/2011. Before the Human Tissue Act 2004 came into force, previous inspections were carried out by HM Inspector of Anatomy, with the last such inspection conducted in October 2005.

The scope of this inspection included visual inspection of the hub and the two satellite facilities, review of relevant documentation at each facility and interviews with members of staff undertaking licensable activities. The review of each facility included a traceability audit. Records relating to cadaveric material were traced back to evidence of consent and checked against inventories and any relevant records of transport and delivery. The traceability audit extended to records relating to specimens that have been respectfully disposed of. All specimens were fully traceable.

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

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The current arrangement for storage of frozen bodies, selected for use in the surgical training courses, does not preserve the dignity of the deceased during storage or during movement of bodies prior to and after use in surgical training courses. The location of two storage units in the dissection room is not suitable as the control and oversight of access afforded to the mortuary and preparation area is not reflected in the dissection room. Standards of storage applied to frozen cadavers differ from the standards applied to embalmed bodies.	**Major**

Advice

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

No.	Standard	Advice
1.	GQ1 School of Life Sciences	The DI is advised to modify the forms used to record transfer of specimens between the hub and the satellite facilities in order to include reference to the condition of specimen on despatch to and return from the satellite facilities.
2.	GQ2 School of Life Sciences	The DI is advised to update the schedule of periodic documented audits to include audits that encompass all of the applicable HTA standards over the course of a two year audit cycle.
3.	GQ7 School of Life	The DI is advised to extend the programme of periodic documented risk assessments to include: • movement of cadavers to task rooms instead of the main dissection room space being used for surgical training courses; and

	Sciences	• maintenance of retained pathology specimens. In particular, the procedure to address specimens that require topping-up of their preservative solution.
4.	PFE3 School of Life Sciences	Following risk assessment of the process for topping-up preservative solution of retained pathology specimens, the DI is advised to implement a programme of restoration, prioritising those specimens that have been identified during audit as most at risk of deterioration.
5.	PFE1 School of Life Sciences	There is evidence that another department located on the floor above the mortuary has had problems with water leaks. This has resulted in occasional ingress of water through the ceiling of the mortuary. Whilst some remedial work has been carried out, it is not clear whether or not the source of all potential leaks has been fully addressed. The DI is advised to liaise with relevant departments to ascertain whether the root cause of the leaks has been fully evaluated and, if so, what steps have been taken to mitigate against future leaks.
6.	PFE3 School of Life Sciences	At the time of inspection, two freezers within the main dissection room and two freezers within the preparation area of the hub facility were seen to be abutting one another, preventing natural dissipation of the heat generated by the freezer chiller mechanisms. The DI is advised to change the location of the freezers to provide an area of clear space around each unit in order to allow heat generated to more easily dissipate. This will prevent undue stress on the chiller mechanisms and reduce the risk of mechanical breakdown.
7.	GQ2 Sutton Bonington Campus	The site visit inspection of The School of Veterinary Medicine and Science, University of Nottingham, Sutton Bonington Campus, provided an opportunity to review standard operating procedures (SOPs) relating to relevant licensable activities. SOPs are in place for all activities and changes are under the control of the Person Designated at the satellite. However, the formal process of approval and change control is not reflected on the SOPs that were available for review during inspection. Consequently, the DI is advised to update the format, content and change control of satellite SOPs to meet standards that are established at the hub facility. This should include but may not be limited to reference to: • author, reviewer and approver of SOP; • version number of SOP; and • date of approval of SOP.
8.	GQ1 Sutton Bonington Campus	The DI is advised to update the Sutton Bonington Campus SOP describing the transfer of cadaveric material between the hub and the satellite to include reference to: • the use of the lockable cabinet for storage of specimens whilst at Sutton Bonington Campus; and • forms and related paperwork to track and trace the transfer of specimens between the hub and the satellite facilities and the temporary storage of specimens at the satellite.
9.		The site inspection of The School of Graduate Entry Medicine and Health Studies, The Royal Derby Hospital, provided an opportunity to review systems and procedures relating to relevant licensable activities. Following review of various documents and discussion on ways of working the following advice

		relates to improving existing systems and procedures. • Following a recent reorganisation, the satellite at The Royal Derby Hospital is now part of the 'Division of Medical Sciences & Graduate Entry Medicine' within the School of Medicine. The DI is advised to put a formal agreement in place between the hub and the School of Medicine. The agreement should be agreed and signed by both parties and cover, but not necessarily be limited to, topics such as responsibility for: bequeathal and consent; transport of specimens; disposal of specimens; and reporting any adverse incidents. The aim of this agreement should be to clearly set out respective roles and responsibilities and to avoid any ambiguity. • The Person Designated at the satellite has a system for tracking and tracing transport of specimens between the hub and the satellite facilities. The system uses a central ledger in conjunction with a series of transfer sheets. The DI is advised to update this system in order to include reference to the condition of specimens on receipt at the satellite and on return to the hub; and to include a 'tick box' mechanism for confirming transfer of information into the ledger from the transfer sheet. These additions will improve the existing system of traceability and provide a mechanism for recording any change to condition of specimens. • The DI is advised to update the change control system that is in place at the satellite facility to ensure that any changes to SOPs that are relevant to licensable activities include the DI within the review and approval process. • Unlike the satellite at Sutton Bonington Campus, the satellite at The Royal Derby Hospital may, on occasions, dispose of human tissue. The DI is advised to update the SOP covering disposal to include reference to the use of the disposal record spread sheet by the Person Designated at the satellite facility and to include the need for the person taking responsibility for disposal to sign / initial the disposal record to reflect responsibility for disposal. • Regular audits are conducted at the satellite facilities and records of audits are retained. The DI is advised to update the relevant SOP to include the need for audits and the results of audits to be reported to the DI. These reports should provide a summary of the audits conducted, the outcome of the audits and details of any corrective and preventative actions arising from audit findings.

Concluding comments

Overall, the HTA found the Designated Individual (DI), the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation. A major shortfall was identified in relation to standard PFE3.

A number of strengths and good practices were identified during the inspection.

The DI has a great amount of relevant experience which dates back over a number of years of working in the same role within the establishment. The DI demonstrates knowledge, understanding and practical application of the HTA anatomy sector requirements. The inspection identified a number of areas where the DI has been involved in the development of systems, processes and ways of working and influenced and promoted compliance with licence requirements.

There is a sound overall structure to the governance of licensable activities. Matters relating

to human tissue are discussed at the periodic 'Human Tissue Management Group' meetings. There is a well established, thoughtful and robust bequeathal process supported by an experienced Bequeathal Secretary. Overall, the processes supporting the acceptance and use of donated bodies are focused on maintaining the dignity of and respect for the deceased donors and to maintaining complete and accurate records of body donations and their use. The DI, in conjunction with the Bequeathal Secretary, has developed and tested a new anatomy bequest database. The secure database is about to be implemented. It will provide a more effective system for registering donations and for tracking and tracing the use of specimens.

The DI has employed good use of the role of 'Persons Designated', at the hub and the two satellite facilities, in order to maintain oversight of licensable activities in accordance with applicable HTA standards and codes of practice. There is evidence of close working arrangements and good communication across the hub and both satellite facilities, and with third parties, such as funeral directors and health care professionals, whose services are relied upon as part of the overall process.

Access to the different areas of licensed premises across all three facilities is well managed and controlled, with access restricted to those who are involved in licensable activities. Undergraduate and postgraduate students are required to attend a presentation from the DI or Persons Designated prior to access to licensed premises.

There is one aspect of licensable activity that requires improvement, specifically the arrangements for storing frozen bodies. This is reflected by the reported major shortfall against HTA standard PFE3. In addition, the HTA has given advice to the DI with respect to a number of areas where existing procedures could be enhanced.

The HTA requires that the DI 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 major shortfall identified during the inspection.

Report sent to DI for factual accuracy: **6 November 2013**

Report returned from DI: **15 November 2013**

Final report issued: **29 November 2013**

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: 10 December 2014

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Independent interpreters are available when appropriate • Information is available in suitable formats
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

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
• Policies and procedures are in place, covering all licensable activities • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system
GQ2 There is a documented system of quality management and audit
• A document control system, covering all documented policies and standard operating procedures (SOPs).

- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

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

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

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

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom

GQ6 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
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
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transportation • Records of transportation and delivery • Records are kept of transfer agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies

- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

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.