Site visit inspection report on compliance with HTA minimum standards

School of Life Sciences, University of 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.**

7-9 July 2015

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.

The School of Life Sciences, University of Nottingham (the establishment) was found to have met all HTA standards.

Particular examples 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

This report refers to the activities carried out at the School of Life Sciences, University of Nottingham (the establishment). The establishment consists of a hub facility at the School of Life Sciences, Nottingham and two satellite sites at the:

- Division of Medical Sciences and Graduate Entry Medicine, Derby
- School of Veterinary Medicine and Science, Sutton Bonington

This is the second routine site visit inspection of the establishment by the HTA. The previous inspection took place in 2013 and resulted in a major shortfall in relation to standard PFE3, which was under the oversight of the HTA and was addressed shortly before this inspection. This latest inspection included a visual inspection of the hub facility and both satellite sites, meetings with members of staff, and a review of documentation at all sites. An audit trail was also conducted at all three sites. A description of the sites and the inspection are described below.

The School of Life Sciences, Nottingham (Hub facility)

The School of Life Sciences, University of Nottingham currently has approximately 260 medical students. The students start anatomy dissection classes in the second term of their first year. The dissection room consists of a main room, with four smaller task rooms, each of which is used for the study of prosections and other human material. All rooms have secure access. The main room holds approximately 24 donor bodies which are used for dissection classes. It has 12 rotating dissection tables with upper and lower body trays which allows for rotation of the bodies. One body is assigned per group of 10-12 students, but only five to six students dissect at any one time. Each body has two waste bags, labelled with the donor number, one for organs and one for tissue removed from the body during dissection. Bags are kept with the body and remain with them for final disposition of the body. During classes,

there are four demonstrators and three or four floating demonstrators.

The University of Nottingham also holds international and local training courses for surgeons and other medical staff. Some of the courses include: surgical training techniques, colorectal laparoscopic and trauma techniques. These courses can be held out of hours and staff are always present.

The School of Life Sciences receives about 50 bequeathed bodies per year. The regular route of accepting bodies into the University is through a dedicated access route involving a lift that is used only for the transfer of bodies. At the time of inspection, the lift was under repair and so the establishment was using their contingency plan for bringing in bodies through the hospital mortuary.

Bodies are prepared by one of three methods: formalin embalming, soft-fix embalming, or freezing without embalming. For the formalin embalmed bodies, a very low concentration formaldehyde solution is used. The soft-fix solution does not use any formalin. Soft-fix embalmed bodies are more flexible and provide a more realistic representation of patients than formalin embalmed bodies. Embalming is done by gravity-feed with pre-made purchased chemicals.

All bodies are labelled with a unique identification number that includes the gender, body number, and year of acceptance. Body parts separated from their bodies are labelled with the body number from which they were removed, and with the body part name. Frozen bodies are each labelled with six tags. A tag is attached to each different body region to ensure traceability when body parts are prosected. Each of the six tags displays the unique identification number. The same system applies to embalmed bodies, which have an additional tag on the abdomen.

There are up to 48 storage spaces in the mortuary cabinets for embalmed bodies, and 20 freezer spaces for frozen bodies. Embalmed bodies are put into body bags and stored at room temperature in designated mortuary cabinets. Frozen bodies do not get embalmed and are put into freezer storage. Frozen bodies are stored at -20 degrees Celsius. The freezer is alarmed and records temperatures digitally (see advice item 7).

Body parts are stored by body part type in the preparation room on shelves in stainless steel storage tanks. Wet specimens are stored in buckets with preservative solution in a secure area of the dissection room. All parts are put in plastic bags and labelled with the unique ID tag.

The school also stores bones and plastinated specimens. All are labelled appropriately and stored in secure areas.

Existing holdings of histological slides, sometimes used for teaching, are stored in a locked cabinet in a secure room in the medical school. Skulls used for teaching are also stored there.

The School of Life Sciences loans specimens to both satellite sites. The Division of Medical Sciences and Graduate Entry Medicine accepts long term loans. The School of Veterinary Medicine and Science accepts short term loans (about 1 week) for comparative anatomy classes. Specimens are transferred between the hub and satellite sites by anatomy staff in a discreet transfer box, preserving the integrity of the specimen.

A traceability audit was conducted on:

- a whole body from the mortuary cabinet;
- a prosection of head, neck and shoulder;
- a prosected heart; and

- a prosected pelvis.

Labelling on the whole body and prosections were cross-referenced with paper records, donor consent forms, transfer records, disposal records and the electronic database. A complete audit trail of consent for retained parts on the prosections was also done. No discrepancies were found.

The Divison of Medical Sciences and Graduate Entry Medicine, Derby campus (Satellite site)

The Divison of Medical Sciences and Graduate Entry Medicine has approximately 85 graduate entry students and 50 students on the BSc courses. Students use prosections only and no dissection is undertaken. The school borrows specimens from the hub site on a long-term basis. Specimens are stored on shelves in a dedicated locked storage area, where the room temperature is kept at 18 degrees Celsius.

The anatomy room consists of a main room, with four surrounding smaller task rooms. All rooms have secure access. Up to 44 students use the prosections at any one time with a member of staff supervising.

Body parts are stored by body part type, bagged with the unique ID number attached, and stored in clear plastic bags. Potted specimens, bones, and some plastinated material are also stored.

A traceability audit was conducted on:

- a posterior thorax and abdomen; and
- a knee joint.

Tags on the specimens were compared with transfer records between sites, the parts register book at Derby and the electronic database at Nottingham. No discrepancies were found.

The School of Veterinary Medicine and Science, Sutton Bonington campus (Satellite site)

The School of Veterinary Medicine and Science, Sutton Bonington campus, has about 134 students. Students can sign up for a session of comparative anatomy classes, where there is a dedicated room for comparative anatomy sessions. Human prosections and human plastinated specimens are used in the sessions. The room has secure access. Students are always supervised by a member of staff.

The human anatomy room houses two cabinets with triple locks on each. One cabinet contains human plastinated specimens that were imported from the USA. The other cabinet holds human prosections borrowed from the hub site. There were no prosected specimens being stored on site at the time of the inspection.

A reverse traceability audit from paper records was conducted on:

- a left and right foot that was transferred from Nottingham to Sutton Bonington and then returned to Nottingham; and
- a whole brain that was transferred from Nottingham to Sutton Bonington and then returned to Nottingham.

Transfer records at Sutton Bonington and Nottingham were compared and no discrepancies were found.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1, C2, C3 Nottingham	The DI is in discussions with the National Repository in Nottingham about establishing a single bequeathal office for both sites. The National Repository gets referrals from the University when they are unable to accept the donor. The referred bodies are then frozen and used in surgical skills training, for which they have consent. If this single bequeathal office is established, then donors will be provided with a second option to donate their body. This will ensure that fully informed consent is met at the time of donation and that the wishes of the donor are met. If a single bequeathal office is established, staff from the University of Nottingham, who are involved in taking consent, are advised to visit the National Repository to familiarise themselves with the work of the Repository and the surgical courses offered. Once the partnership between the University of Nottingham and the National Repository is finalised, the DI is advised to establish formal protocols.
2.	GQ1 Nottingham	The DI is advised to change the Quality manual to state that the anatomy licence covers **storage** for public display only and not public display itself. The DI is advised that training a group of students from outside the University that involves looking at or using prosections is not considered public display.
3.	GQ1 Derby and Sutton Bonington	The DI may wish to consider establishing further links between the Divison of Medical Sciences and Graduate Entry Medicine and the School of Veterinary Medicine and Science. This will open up new channels of communication between the satellite sites where they can share resources and exchange information for best practice.
4.	GQ2 Nottingham, Derby and Sutton Bonington	Thorough audits take place at the hub and satellite sites. In order to strengthen these audits, the DI is advised to record the condition of each specimen during the audits. This will highlight specimens which need to be restored or disposed of.
5.	GQ5 Sutton Bonington	In 2013, the School of Veterinary Medicine and Science imported plastinated human specimens from the USA. At the time of inspection, a certificate of origin or evidence of consent for use of the material was not available. However this was later provided to the HTA after staff contacted the company from which the specimens were obtained. Staff are advised to ensure that all information relating to imported material is recorded and retained to ensure traceability.
6.	PFE5 Nottingham, Derby and Sutton	The risk of environmental formaldehyde levels exceeding acceptable limits is low due to the low concentration of formalin in the embalming chemicals. However, to ensure that health and safety standards are met, the DI is advised to seek further advice from the person who has formal responsibility for biological safety matters.

	Bonington	
7.	PFE5 Nottingham	New upright freezers were installed to replace the chest freezers. The DI is advised to develop a documented procedure for testing the freezer alarm which should also explain how such tests are recorded. This will help ensure that the integrity of the bodies is not compromised when staff are not present.

Concluding comments

During the site visit inspection of the establishment, several areas of strengths and good practice were noted. These were:

- staff are experienced and knowledgeable about the activities carried out at the establishment. They also demonstrated a good understanding of the Human Tissue Act 2004 and how it related to them;
- there are detailed SOPs and risk assessments that cover all activities;
- the establishment has a robust bequeathal process and an effective database that ensures traceability of the donor body and parts from consent to disposal;
- staff engage students in the donor process by having them complete an audit involving a checklist of tissue or parts retained from the body along with staff before disposal;
- at least one member of staff attends every cremation; and
- thorough audits of material are conducted at all the sites.

The HTA has given advice to the Designated Individual with respect to a number of areas where existing procedures could be enhanced.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 23 July 2015

Report returned from DI: 11 August 2015

Final report issued: 11 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
• 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 visits.

   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.