**Site visit inspection report on compliance with HTA minimum standards**

**Institute of Learning and Teaching**

**HTA licensing number 12022**

**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.**

**13 August 2013**

## Summary of inspection findings

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.

Institute of Learning and Teaching (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

The establishment provides education and training for approximately 1200 students each year across a range of disciplines, encompassing medical, dental and other allied health students, at undergraduate and postgraduate level. The establishment also hosts continuing professional development sessions for surgeons on its premises.

This was the establishment's first, routine inspection since issue of its licence in 2008. Prior to this the establishment was inspected on a number of occasions by Her Majesty's Inspector of Anatomy. The previous reports were seen on inspection and the findings were noted as favourable. This inspection encompassed document review, interviews with staff and a visual inspection of the bequeathal office, body reception centre, mortuary, walk-in fridge with stored prosections, dissection room and the Human Anatomy Resource Centre (HARC). All sites visited were highly secure. The bequeathal records were held in fireproof filing cabinets. Only five members of staff, and university security, have access to the mortuary. Students are always supervised by staff in the HARC and in the dissection room.

The bequeathal officers facilitate the consent process. The establishment has a database of approximately 8000 potential donors. After a potential donor has died, bequeathal officers are informed and determine whether a donation should be accepted. Donors with an illness or medical condition which might affect their suitability for anatomical examination are cases are discussed with medically trained staff.

The area where bodies are received is discreet and there are plans to improve the premises. This includes adding a carport and cameras for additional security. The mortuary has 27 fridges. The temperature is monitored manually by staff, although all bodies are embalmed before storage. The establishment keeps a store of prosections in a walk-in fridge adjacent to the mortuary. Prosections are checked regularly by anatomy technicians to confirm their continued suitability for educational purposes. The establishment is planning a refurbishment of its reception area to install 40 fridges, in order to ensure continued provision of a high-quality service. Once these are installed, the current, older bank of fridges will be used for contingency arrangements.

Bodies are only accepted with the correct forms. Once accepted, a unique donor number is assigned to the body and all bodies and prosections are also tagged with this number.

A traceability audit was completed on the following number of cases:

- an embalmed body stored in the mortuary fridge and awaiting dissection;
- a research tissue sample in a container in the mortuary;
- a prosection from the walk-in fridge;
- a whole embalmed body on a table in the dissection room;
- a prosection in a cupboard in the dissection room; and
- a prosection in the cooler fridge in the HARC.

For the prosections and whole bodies, a paper list, continuously updated by the establishment to track the location of bodies and parts throughout the Institute, was checked. No anomalies were found.

For each of the cases, the following documents were reviewed:

- donor consent form;
- “HTA3 form” (“medical certificate of registered cause of death”) or a modern version of this, depending on when body was accepted for donation;
- the ‘after death’ checklist, which notes basic donor information and, on the reverse, tick box questions to confirm donor health conditions, when determining whether to accept a donation post mortem;
- donor details book, including details such as donor name & address, date of birth, date of death and, where applicable, date of disposal of tissue; and
- the “application for cremation” form completed at time of death, indicating family’s wishes for cremation/burial.

In addition, the electronic database was cross-referenced for some of the samples and the paper inventory of stock and cadaver retention forms, held by the anatomy technician were reviewed.

Anomalies were found in only one of the cases checked. These did not affect traceability. The establishment has confirmed it will follow this particular case up. Advice is provided below against standard GQ5.

Details from a donor consent form were also traced to the electronic database. No anomalies were found. The establishment collects consent to retain bodies and body parts beyond three years, however has a general policy to arrange burial or cremation after three years. The anatomy technician uses a coloured tagging system for bodies and parts to note donors that are ready for burial or cremation. The bequeathal officer is informed when a funeral should be arranged and liaises with the family if required and the establishment's contracted provider to organise this. Files for deceased donors were also reviewed. No anomalies 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 |
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| 1. | C1 | Staff at the establishment obtain consent in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA code of practice on consent. The consent documents observed during the inspection included the use of the HTA name and logo on the forms. The DI and relevant staff at the establishment are requested to review the latest version of the "Use of HTA logo and branding policy April 2012" and ensure that its documents comply with the current policy. Available at:<br><br>http://www.hta.gov.uk/termsandconditions/copyright.cfm<br><br>The establishment is also advised to continue to review its consent information and forms as necessary in line with any changes to its practices. |
| 2. | GQ1 | All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process. The DI is advised to make minor amendments to the following standard operating procedures (SOPs) in line with its current practices:<br><br>*SOPLVADMIN012, Rejection at application stage*: There is an additional notes section on SOPs. It may be useful to note in that section details about the referral of donated bodies to other centres in cases where donors have widespread malignancy.<br><br>*HARCSOP0011, Measuring formaldehyde levels in the dissecting room:* The DI should consider updating this section to include acceptable parameters and reflect the current use of a sensor to measure formaldehyde levels. |

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| 3. | GQ5 | The establishment has a coding and records system facilitating the traceability of bodies, body parts, tissues and cells. There was one anomaly found during the traceability audits on a number of cases, although this did not affect traceability. The establishment is advised to continue its current system of internal audits to control this type of discrepancy.<br><br>The establishment also holds a number of bones, which are older than 100 years and / or obtained prior to the introduction of the Human Tissue Act 2004. The establishment holds many of these in the mortuary in boxes. The establishment is advised to catalogue the contents of the boxes, to enable better labelling and tracking of these holdings. |
| 4. | GQ7 | The establishment has documented risk assessments for all practices and processes. The majority of these relate to health and safety considerations. The establishment is advised to consider other factors related to traceability when conducting future risk assessments, such as potential risk of mix-up of prosections, or risk of continued storage of existing holdings, to continue to ensure public confidence is maintained in the donation process. |
| 5. | PFE1 | The establishment's premises are fit for purpose. The DI is advised to assure himself that risks, such as those relating to security, storage and donor confidentiality, are considered as part of planned refurbishment of the premises. |

**Concluding comments**

There were a number of areas of strengths and good practice seen during the inspection. The establishment's practices and premises support an environment that promotes dignity for the deceased. This respect for the contribution made by donors is communicated to all staff and students through induction, training, and special events, such as a three yearly memorial service to honour the valuable contributions made by donors to education and training at the establishment.

Great care is taken with the consent process, for example, following the introduction of the HT Act, the establishment followed up with all families of donors with pre-2006 consent forms, to seek instruction on taking photographs and whether body parts could be retained for more than three years.

The HTA has given advice to the Designated Individual with respect to consent forms, standard operating procedures, traceability audits and risk assessments. Prior to publication of the final report, the establishment acted in line with the advice given against C1, GQ1 and GQ5 and has confirmed its commitment to addressing the advice given against GQ7 and PFE1 in due course.

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

**Report sent to DI for factual accuracy: 23 August 2013**

**Report returned from DI: 6 September 2013**

**Final report issued: 20 September 2013**

## 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 |
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| **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<br>• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose<br>• 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<br>• Independent interpreters are available when appropriate<br>• 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<br>• Evidence of suitable training of staff involved in seeking consent<br>• Records demonstrate up-to-date staff training<br>• Competency is assessed and maintained |

| Governance and quality system standards |
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| **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<br>• Appropriate risk management systems are in place<br>• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes<br>• 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 |
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| **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<br>• Policies in place to review and maintain the safety of staff, authorised visitors and students<br>• 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<br>• The premises have sufficient space for procedures to be carried out safely and efficiently<br>• 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<br>• Air classification system and maintenance of air quality, including control and monitoring of environmental conditions<br>• Documented cleaning and decontamination procedures<br>• 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<br>• Critical storage conditions are monitored and recorded<br>• 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<br>• A system is in place to ensure that traceability of relevant material is maintained during transportation<br>• Records of transportation and delivery<br>• Records are kept of transfer agreements with recipients of relevant material<br>• 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 |

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

| **Disposal Standards** |
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| **D1 There is a clear and sensitive policy for disposing of human organs and tissue** |
| • Documented disposal policy<br>• Policy is made available to the public<br>• 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<br>• 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.