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

**University of Liverpool**

**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.**

**11 December 2018**

## Summary of inspection findings

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

University of Liverpool (the establishment) was found to have met all HTA standards.

**The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

**Background to the establishment**

This report refers to activities carried out at the University of Liverpool (the establishment) in the Human Anatomy Resource Centre (HARC). The Designated Individual (DI) is a Professor of Anatomy and Cell Biology. The Corporate Licence Holder (CLH) is the University of Liverpool and the CLH contact (CLHc) is the Executive Pro-Vice Chancellor. There are a number of Persons Designated (PDs) responsible for undertaking licensable activities named on the licence including the Bequeathal Secretary, the Technical Manager, Anatomy Lecturers and Demonstrators and the Director of HARC.

The establishment has been licensed by the HTA since July 2007 and this is the second routine site visit inspection. The establishment is a teaching facility that provides anatomy and pathology teaching, training and resources to students and healthcare professionals. This includes undergraduate and postgraduate programmes and continuing professional development (CPD) courses. The department consists of teaching rooms, a dissection room and prosection area, a mortuary and multiple body storage areas. All areas are covered by closed circuit television (CCTV), alarm systems and restricted swipe card access. The teaching areas are accessible by establishment staff and authorised students whereas the body store areas are restricted to technical staff, the DI and the Director of HARC.

The establishment receives approximately 50 whole body donations per year. They operate a bequeathal process and obtain donated bodies from donors who fit established acceptance criteria. Occasionally, they receive referrals from other anatomy schools; for example, when other schools have a sufficient number of bodies. The establishment does not import bodies or prosections from outside of the UK. The Bequeathal Secretary is responsible for the consenting process. Upon request, bequeathal packs are sent out to potential donors containing detailed information sheets and a consent form. Approximately 20 packs per week are requested by telephone. Members of the public are also able to download the pack online. An average of 15 forms are returned each week. Once consent forms are returned they are subject to validation checks then scanned in to the database and the donor is registered on the system.

Delivery of bodies is arranged, in advance, with a contracted funeral director. On arrival, the funeral director enters an enclosed loading bay. On receipt of a body, identification and consent documentation are checked and all bodies are labelled with a sequential unique identification number (ID). One tag is put on every donor. The establishment uses a database for tracking bodies from arrival to use and then to disposal. Bodies are embalmed primarily using formalin; however the establishment also has Thiel embalming facilities that are predominantly used for postgraduate project work. Freezers are utilised if fresh frozen material is required and stored. If there is a requirement for prosected specimens, establishment staff dissect and prepare specimens. Prosections are labelled with a unique identification number (which relates to the donor) and a letter (which relates to the year of preparation).

Bodies and prosections are stored in multiple storage areas within HARC. Whole cadavers are stored in locked fridges or freezers and Thiel embalmed bodies are stored in the Thiel tanks. Temperature controlled storage facilities are maintained on annual service contracts and temperatures are monitored. All body store areas are alarmed should temperatures deviate outside of set ranges.

Anatomical examination by anatomy students takes place within the dissection room. During dissection classes, students are supervised by teaching staff, technicians and demonstrators. Before undertaking any practicals, students are required to attend an introductory lecture which includes information about the Human Tissue Act 2004 (HT Act) and an overview of the regulatory framework. Students are also required to read and sign a Code of Practice containing the establishments' rules and regulations. Students register either electronically or on a paper register when attending classes. They are also required to wear appropriate personal protective equipment (PPE). The medical students undertake a systematic dissection of a whole cadaver over the course of three years. Any residual tissue removed during dissection is kept with the body then transferred into a waste bin specific for the cadaver. The material is reunited with the body prior to disposal. Disposals are arranged in advance and bodies are put into individual coffins provided by the funeral director. Bodies are kept for approximately three years before disposal. If there is no permission for retained parts, these are reunited with the rest of the body prior to disposal. Families are given the option to attend the cremation and a ceremony is provided.

**Description of inspection activities undertaken**

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the DI, communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and interviews with key members of staff including the Bequeathal Secretary, Technical Manager, the Director of HARC and a Lecturer. The inspection also included a visual inspection of the areas where samples are stored under the licence and audits of sample traceability. Audits of the following, randomly-selected samples were conducted:

- two whole embalmed bodies stored in the fridge;
- a whole embalmed body stored in the Thiel tank;
- a whole embalmed body currently in use stored on the dissection table;
- one prosection stored in the cold room, and;
- five prosections stored in the teaching rooms.

For the prosections and whole bodies, a paper list, continuously updated by the establishment to track the location of bodies and parts throughout HARC, was checked. For each of the cases, the consent documentation was reviewed, including any permissions for parts to be kept. There were no discrepancies found in consent documentation completed after the Human Tissue Act 2004 came into force. However, one discrepancy was identified for an existing holding that originated from a body under the previous legislation. The DI confirmed that this specimen would not be retained and it was subsequently sent for disposal.

**Inspection findings**

The HTA found the CLH, the DI, the premises and practices 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(a) | The DI is advised to include the Medical Certificate of Cause of Death (MCCD) to the bequeathal checklist. Although the establishment ensures that the MCCD has been issued and signed, it is not currently specified on the checklist. |
| 2. | C2(b) | The DI is advised to ensure that there is refresher training in place to ensure that proficiency in seeking consent is upheld. Although records demonstrate up-to-date staff training, there is a variation in the length of time staff have been in post |
| 3. | GQ1(a) | An establishment should not use the HTA's logo on documentation as it implies our endorsement. The DI is asked to remove the HTA logo from the establishment's internal documentation (HT7 form). |
| 4. | GQ1(a) | The DI is advised to implement a system by which staff acknowledge that they have read and understood relevant SOPs. This will provide an assurance that staff are fully informed of the written procedures so that they reflect actual practices. |
| 5. | GQ2(a) | The DI is advised to include a check that a valid MCCD has been issued and signed for each donation in the annual audit. This will strengthen the audit |

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|---|---|---|
| | | process to include all documents that are required by law to store a body for anatomical examination. |
| 6. | GQ3(a) | The DI is advised to ensure that all staff involved in undertaking licensed activities are aware of the requirements of the HT Act and the HTA's Codes of Practice. Currently, the induction process includes an informal discussion about licensable activities and the HTA was informed during inspection that the establishment are looking into incorporating HTA training into annual staff PDRs. |
| 7. | PFE1(a) | The fridges in the teaching room are currently not labelled. The DI is advised to clearly label them to ensure that staff do not inadvertently store specimens in the wrong fridge. |
| 8. | PFE2(c) | There was one, unmonitored standalone fridge/freezer unit containing human material. Although refrigerated storage conditions were not critical as material was embalmed, the DI is advised to ensure all temperature controlled units storing relevant material are monitored, maintained and storage conditions acted on when required. |

**Concluding comments**

This report outlines the second routine inspection of the establishment.

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

The University of Liverpool (the establishment) was found to have met all HTA standards.

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

**Report sent to DI for factual accuracy: 21 December 2018**

**Report returned from DI: 10 January 2019**

**Final report issued: 10 January 2019**

## 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** |
| a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.<br>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.<br>c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.<br>d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.<br>e) Language translations are available when appropriate.<br>f) Information is available in formats appropriate to the situation. |
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** |
| a) There is suitable training and support of staff involved in seeking consent.<br>b) Records demonstrate up-to-date staff training.<br>c) 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** |
| a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.<br>b) There is a document control system.<br>c) There are change control mechanisms for the implementation of new operational procedures.<br>d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff.<br>e) There is a system for managing complaints. |
| **GQ2 There is a documented system of audit** |
| a) There is a documented schedule of audits covering licensable activities.<br>b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these. |
| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills** |
| a) Qualifications of staff and all training are recorded, records showing attendance at training.<br>b) There are documented induction training programmes for new staff.<br>c) Training provisions include those for visiting staff.<br>d) Staff have appraisals and personal development plans. |

| GQ4 There is a systematic and planned approach to the management of records |
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| a) There are suitable systems for the creation, review, amendment, retention and destruction of records.<br>b) There are provisions for back-up / recovery in the event of loss of records.<br>c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing). |
| **GQ5 There are systems to ensure that all adverse events are investigated promptly** |
| a) Staff are instructed in how to use incident reporting systems.<br>b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made. |
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** |
| a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.<br>b) Risk assessments are reviewed regularly.<br>c) Staff can access risk assessments and are made aware of risks during training. |

| Traceability standards |
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| **T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail** |
| a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.<br>b) A register of donated material, and the associated products where relevant, is maintained.<br>c) An audit trail is maintained, which includes details of when and where the bodies. or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom.<br>d) A system is in place to ensure that traceability of relevant material is maintained during transport.<br>e) Records of transportation and delivery are kept.<br>f) Records of any agreements with courier or transport companies are kept.<br>g) Records of any agreements with recipients of relevant material are kept. |
| **T2 Bodies and human tissue are disposed of in an appropriate manner** |
| a) Disposal is carried out in accordance with the HTA's Codes of Practice.<br>b) The date, reason for disposal and the method used are documented. |

| Premises, facilities and equipment standards |
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| **PFE1 The premises are secure and fit for purpose** |
| a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.<br>b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.<br>c) There are documented cleaning and decontamination procedures. |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** |
| a) There is sufficient storage capacity.<br>b) Storage arrangements ensure the dignity of the deceased.<br>c) Storage conditions are monitored, recorded and acted on when required.<br>d) There are documented contingency plans in place in case of failure in storage area. |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** |
| a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.<br>b) Users have access to instructions for equipment and are aware of how to report an equipment problem.<br>c) Staff are provided with suitable personal protective equipment. |

## 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.