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

**St George's, University of London**

**HTA licensing number 12330**

**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.**

**31 October 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.

Although the HTA found that St George's, University of London had met the majority of the HTA's standards, two major shortfalls and two minor shortfalls were found against standards relating to Governance and quality systems and Premises, facilties and equipment. The condition of the refrigerated body store was of particular concern as it fell short of our expected 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 St George's, University of London (the establishment). The Designated Individual (DI) is the Head of Anatomical Sciences and Reader in Anatomy, the Corporate Licence Holder (CLH) is St George's, University of London and the CLH contact (CLHc) is the Chief Operating Officer.

St George's, University of London has been licensed by the HTA since 2007 and this is the second routine inspection. The last inspection was in 2009. The licence covers one building which houses the Anatomy Department.

The establishment is a teaching facility that provides anatomy and pathology teaching, training and resources to students and healthcare professionals. This includes undergraduate, postgraduate and surgical education. The Department consists of a large dissection room (DR) containing storage facilities, prosection area, refrigerated storage area and the pathology museum. The Anatomy Department is a secure area with restricted access and is only accessible by establishment staff and several named and authorised students. It is alarmed out of hours.

The pathology museum contains over 2,100 pathological specimens, which are all existing holdings. This is a closed collection, used for teaching and training of student; access is restricted to University and Trust staff, and authorised and supervised persons.

All body donations are received through the London Anatomy Office (LAO). The establishment receives approximately 50 body donations a year, the consent for all of which is managed by the LAO. Bodies are received through the mortuary entrance and transported to the adjacent Anatomy Department by funeral directors. Transport arrangements are organised by the LAO through contracted funeral directors and are always within working hours. On receipt of a body, identification and consent documentation are checked and all bodies are labelled with a unique identification number (ID). Two tags with the unique ID are put on every donor. Bodies are embalmed on-site by trained staff and during the inspection the establishment informed the HTA that they are planning to begin embalming bodies for other establishments. When a body is to be released, disposal is carried out in line with the family's and donor's wishes by the LAO, which organises the collection of the body. Occasionally, the establishment loans specimens to other Universities and suitable agreements are in place to accommodate this. The establishment uses an electronic database and a subject register for tracking bodies from arrival to use to disposal.

At the beginning of the academic year, University students are thoroughly briefed, sign a Code of Conduct and are reminded of the local rules each time they enter the DR. For external courses that are conducted at the establishment, it is the course leader that is

responsible for signing the legal agreements, Code of Conduct and local rules. These are then conveyed to course participants.

The establishment stores whole bodies, whole skeletons, prosections, pathological, former anatomical and plastinated specimens. The DR holds up to 24 cadavers - on separate dissection tables for the academic year - each labelled with identifiers on the table and tags on the ear and toe. The establishment purchases fresh frozen cadaveric heads from commercial suppliers in the USA that are stored in two chest freezers in the DR room (see Advice, item 8). The DR contains two banks of freezers that contain whole bodies and two banks of fridges where prosections are stored where there has been consent for retention.The prosection area stores a number of former anatomical specimens and potted specimens. The DR also contains a number of plastinated specimens.

The refrigerated body store has capacity for up to 45 bodies on racking and is currently in a substandard condition (see shortfall against PFE2(b)). The area has not been regularly cleaned and is in a dire condition. Many trays were uncleaned and overspilling with body and embaliming fluids. In addition, blood was observed on the floor and trays which had not been cleaned for a period of time.  Due to the poor condition of the refrigerated body store, the dignity of the deceased has been compromised and it also presents health and safety risks to staff working in this area.

**Description of inspection activities undertaken**

The inspection comprised: a visual inspection of all areas of licensable activity; interviews and roundtable discussions with the DI, Director of Anatomical Sciences, Anatomy Prosector, Dissecting Room Senior Technician, Administrator and Bequeathals Secretary and the Pathology Museum Manager; a thorough document review of all policies and procedures relating to the licensed activities. Receipt and disposal procedures were inspected and traceability audits were conducted.

Traceability audits were carried out on four cadaveric heads from the chest freezer, two whole bodies from the freezers, two prosections, two potted specimens and two other pathology specimens. Labels and tags on bodies were noted and checked against documentation, including electronic databases and consent forms (see Advice, item 1). Bodies are assigned a unique, sequential identifier by the establishment when they are received, along with the number assigned by the LAO. These identifiers, along with date of receipt, are recorded on all relevant documentation and databases. No anomalies were found.

## Inspection findings

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

## Compliance with HTA standards

### Governance and Quality

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ2 There is a documented system of audit. | | |
| b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these. | There is no documented schedule of audits and audit reports do not contain sufficient information and details on audit findings. | **Minor** |
| 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. | The establishment does not have risk assessments relating to compliance with the HT Act and HTA's Codes of Practice, and which cover the risks to the bodies and tissue.<br>Although risk assessments for specific SOPs are generated, documented risk assessments for the establishment that were provided during the inspection did not include sufficient details of the risks to the tissue and the mitigating actions. | **Minor** |

**Premises, Facilities and Equipment**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| PFE1 The premises are secure and fit for purpose. | | |
| c) There are documented cleaning and decontamination procedures. | Despite the presence of a cleaning SOP, there was no evidence of regular cleaning of licensed areas and it was clear that areas such as the refrigerated body store had remained uncleaned for extended periods of time. The poor condition of this area presents health and safety risks to staff.<br>Cleaning needs to be subject to a schedule and recorded.<br>See Advice, items 7 and 8. | **Major** |
| PFE2 There are appropriate facilities for the storage of bodies and human tissue. | | |
| b) Storage arrangements ensure the dignity of the deceased. | The refrigerated storage area is not subject to regular cleaning and was extremely dirty. There were several overflowing and uncleaned trays, some with the deceased laid face down.<br>In addition, body fluids, embalming fluid and blood were observed on the floor and on trays.<br>Cadaveric heads, awaiting disposal in the chest freezers, were not bagged separately.<br>These conditions compromise the dignity of the deceased. | **Major** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1(a) | The DI is reminded that staff must adhere to the establishment's agreed processes. SOPs mandate that identification tagging must be on the ear and toe of the deceased but this was not always seen to be the case. In addition, the cleaning SOP has also not been followed correctly as some areas were found to be dirty. |
| 2. | GQ1(a) | The DI is advised that an additional procedure, to cover the performing of body checks to assess the condition of bodies stored in the refrigerated body store for leakage and damage, would be useful in maintaining the dignity of the deceased. |
| 3. | GQ2(a) | To improve the effectiveness of the establishment's approach to audit, the DI is advised to develop a documented audit schedule, which should include procedural and process audits, traceability audits including cadavers, prosections and any other specimens. |
| 4. | GQ2(b) | The DI is advised to record details of the audit findings including any audit findings and corrective and preventative actions taken in response to these findings. |
| 5. | GQ5(a) | Adverse events SOP (SOP20) details only how to manage complaints. The DI is advised to include a section on identifying incidents relating to human tissue and how staff report these incidents. |
| 6. | T1(b) | The DI is advised to repair the feet of the skeletons in the dissection room to ensure full traceability is maintained for all the associated material. |
| 7. | PFE1(c) | The DI is advised to strengthen the SOP for cleaning (BMS SOP6) to include all areas of the refrigerated body store, including trays and drains. If bodies are expected to leak regularly, additional cleaning processes need to be implemented and adhered to. |
| 8. | PFE3(c) | The DI is advised to remind staff to wear all available PPE at all times when necessary. For example, if the ground of the cold store regularly has body fluids on it, overshoes should be worn when in this area. |

## Concluding comments

There are a number of areas of practice that require improvement, including two major shortfalls and two minor shortfalls.The HTA had significant concerns about the condition of the refrigerated body store, which compromises the dignity of the deceased stored within and poses risks to staff. It appeared that the refrigerated body storage area had been in maintained in a poor condition for some time.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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 shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 23/11/2018**

**Report returned from DI: 10/12/2018**

**Final report issued: 12/12/2018**

**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: 03/06/2019**

## 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 |
|---|
| **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 |
|---|
| **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** |
|---|
| 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** |
|---|
| **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.