Site visit inspection report on compliance with HTA licensing standards

Imperial College London

HTA licensing number 12235

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.**

12 June 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 Imperial College London had met the majority of the HTA's licensing standards, six minor shortfalls were found against standards relating to documentation, audit, risk assessments and premises.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

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 Imperial College London (the establishment). The Designated Individual (DI) is the Head of Regulatory Compliance, the Corporate Licence Holder (CLH) is Imperial College London and the CLH contact (CLHc) is the Faculty Operations Officer.

Imperial College London has been licensed by the HTA since 2008 and this is the second routine inspection. The licence now only covers one building at Charing Cross Hospital NHS Trust, which encompasses the Human Anatomy Unit (HAU), the Pathology Museum and the Central Biological Services (CBS). At the time of the last inspection, licensed activities extended to two additional satellites: the Burlington Danes Building and the Department of Psychological Medicine at St Bernard's Hospital Ealing, which also stored the former Corsellis Collection. The Corsellis Collection has since been disposed and both satellites are due to be revoked following this inspection as no licensable activities, pertaining to this licence, are undertaken at them.

The HAU is a teaching facility that provides anatomy and pathology training and resources to students and healthcare professionals. This includes undergraduate, postgraduate and surgical education along with core surgical anatomy and trauma courses. The Unit consists of a dissection room (DR), anatomy skills laboratory and the pathology museum. The pathology museum contains over 2,500 pathological specimens, which are all existing holdings. Additional older pathology and anatomical specimen collections are stored in the CBS. These are both closed collections and access is restricted to University and Trust staff and authorised and supervised persons.

The establishment is involved with all licensable activities and all body donations are received through the London Anatomy Office (LAO). Bodies are embalmed on site by trained staff. The establishment no longer embalms bodies for other establishments. The establishment receives approximately 50 body donations a year, the consent for all of which is managed by the LAO; however, consent records are kept on site. Bodies are received through the mortuary entrance and transported to the HAU through shut-off lifts. Transport arrangements are organised by the LAO through contracted funeral directors and are always in working hours. When a body is to be released, disposal is done in line with the families and donor wishes by the LAO, which organises the collection of the body. Occasionally, the establishment loans cadavers and/or specimens to other Universities and suitable agreements are in place to accommodate this.

There is a large seminar room, which holds up to 40 people, where delegates are briefed and receive introductory training prior to entering the DR. At the beginning of the course, students sign a Code of Conduct and are reminded of the local rules each time they enter the DR.

Delegates receive a Code of Conduct electronically prior to the course and are reminded of this in the briefing.

The establishment stores whole bodies, prosections, pathological and anatomical specimens and bones. The DR stores up to 32 donations, each labelled with identifiers on the body bag and tags on the ear and ankle. Approximately 240specimens are stored in prosection tanks and are tagged and microchipped, to maintain traceability. The DR also contains a small number of animal specimens in sealed pots for comparative anatomy, that are stored separately, and plastinated specimens.

The body store has capacity for 66 bodies, with an additional eight fridge/freezer spaces and contingency racking in place. There is a leak on the ceiling of the body store which has resulted in the significant movement of bodies in recent months, in an attempt to prevent mould spores and protect the dignity of the deceased (see shortfall, PFE2(b)). It is a secure area with restricted access and is only accessible by HAU staff. The establishment receives no fresh frozen specimens. The Anatomy Skills laboratory is a multi-purpose space and human skeletons are stored in locked cabinets with restricted access. The bone store consists of a large collection of existing holdings, including donations from founding medical schools of Imperial College School of Medicine, and a fetal pot collection.

Description of inspection activities undertaken

The inspection comprised: a visual inspection of all areas of licensable activity; interviews and roundtable discussions with the DI, CLHc, Human Anatomy Manager, a Senior Teaching Fellow, the Embalming Officer, an Anatomy Prosector Technician, an Anatomy Technical Officer, the Professor of Anatomy for the Department and the Pathology Museum Technician and; 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 two bodies from the DR, two bodies from the body store, an upper limb prosection and a plastinated specimen. Labels and tags on bodies were noted and checked against documentation, including electronic databases and consent forms. 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 and the Designated Individual to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's 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.	A number of governance documents and SOPs have recently been reviewed but do not reflect current practice and require further updating. These include, but are not limited to: Procedure for Embalming using Soft Fix Solution (FC 4.1) states that every subject is placed into refrigeration after embalming. This is not always true to practice. Procedure for Preparing 1% Phenol Preservation Fluid (FC 34). The fluid is often prepared at 0.5% Phenol and this should be noted in the document for the purposes of learning and induction of new staff. (See *Advice*, item 2*).*	**Minor**
GQ2 There is a documented system of audit.		
a) There is a documented schedule of audits covering licensable activities.	Currently, there is no documented schedule of audits covering licensable activities (See *Advice*, item 4). Although the establishment conducts an annual 'maintenance inventory' of specimens, these are not appropriately documented and findings are not shared with staff members for future learning.	**Minor**

b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	Although there are regular inventory logs of specimens, there has been one audit report evidenced that had sufficient detail in the last 12 months. Audit reporting is not consistent and does not contain sufficient detail related to audit findings (See *Advice*, item 5).	**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 HAU does not have risk assessments relating to compliance with the HT Act and HTA's Codes of Practice, and which cover the risk to the bodies and tissue. Although risk assessments for specific courses are generated, documented risk assessments for the HAU 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.	Although the establishment undertakes regular cleaning of licensable areas, these need to be documented on a cleaning schedule and recorded.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) Storage arrangements ensure the dignity of the deceased.	There is a leak in the ceiling of the body store, which often allows through water which has resulted in the ceiling been taken down on one occasion, deep cleans and movement of bodies over the past months.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The DI is advised to update the Quality System Conduct document to reflect HTA Codes of Practice and Standards that were brought into force in April 2017. Additionally, the references to the satellite sites that are to be revoked should be removed from this document.
2.	GQ1(a)	Several working documents do not reflect current practices. The DI is advised to amend these documents to, provide up to date information on procedures.
3.	GQ1(a)	The DI is advised to include the CLHc on the 'Management & Relationships of HAU Staff Organogram' (FC1) as they have a fundamental role within the governance of the HTA licence.
4.	GQ2(a)	To improve effectiveness of the establishments 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. These audits should have a defined time frame of when they take place.
5.	GQ2(b)	Audit findings need to record details of the audit and corrective and preventative actions taken.
6.	T1(c)	The establishment occasionally loans bodies and specimens to other establishments for education, training and research. The 'Loan Forms' used for this process are not always completed fully and contain little or no information relating to the reason for the loan. The DI is advised to include a summary of the purpose of the loan and timeframe in order to strengthen traceability.
7.	PFE3(a)	The establishment and DI are advised to keep records of their documentation pertaining to ventilation and equipment maintenance on site.

Concluding comments

There are a number of areas of practice that require improvement, including six minor shortfalls.

A number of strengths and areas of good practice were observed during the inspection:

- The establishment is supported by a specialised and dedicated team at the HAU, who appear to work and communicate well with each other, with good engagement from the DI and CLHc. All members of staff appear to hold the dignity of the deceased as one of their core values.

- The establishment microchips all anatomical prosections to further strengthen the traceability of bodies and tissue.

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: 10/07/2018

Report returned from DI: 26/07/2018

Final report issued: 30/07/2018

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: 23/05/2019

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. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. 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. 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. e) Language translations are available when appropriate. 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. b) Records demonstrate up-to-date staff training. 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. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff. 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. 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. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. 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. b) There are provisions for back-up / recovery in the event of loss of records. 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. 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. b) Risk assessments are reviewed regularly. 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. b) A register of donated material, and the associated products where relevant, is maintained. 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. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. 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. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
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. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. 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. b) Storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. 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. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. 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.