Site visit inspection report on compliance with HTA licensing standards

Queens University Belfast

HTA licensing number 12113

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.**

30 July 2019

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 Queens University Belfast (the 'establishment') was found to have met the majority of the HTA's licensing standards, three minor shortfalls were identified against the Consent, Governance and quality systems and Premises, facilities and equipment standards.

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.

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 Queens University Belfast (the 'establishment'). The Designated Individual (DI) is a Lecturer in the Centre for Biomedical Sciences Education. The Corporate Licence Holder (CLH) is Queens University Belfast and the CLH contact (CLHc) is the Pro-Vice Chancellor for Research and Enterprise. There are a number of Persons Designated (PDs) responsible for undertaking licensable activities named on the licence including the Bequeathal Secretary, Bequeathal Coordinators, Technical Staff and Lecturers.

The establishment has been licensed by the HTA since June 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 two dissection rooms, an anatomy teaching area store room containing the majority of prosections, a mortuary, a potted specimen room and teaching rooms. The main entrances are covered by closed circuit television (CCTV) and have restricted swipe card access.

Typically, the establishment receives 25-30 whole body donations each year. They operate a bequeathal process and obtain donated bodies from donors who fit established acceptance criteria. The establishment does not import bodies or prosections from outside of the UK. The Bequeathal Secretary in conjunction with the Senior Mortuary Technician coordinate and manage the donation process (see shortfall against C2(b)). Upon request, bequeathal packs are sent out to potential donors, containing detailed information sheets and a consent form. Returned consent forms are subject to validation checks, following which the donor can be registered on the system. Delivery of bodies is arranged, in advance, with a contracted funeral director (see *Advice*, item 3). On arrival, the funeral director enters the mortuary via a private University road (see shortfall against PFE1(a)). On receipt of a body, identification and consent documentation are checked and all bodies are labelled with a sequential, unique identification code. Two tags are put on every donor. Bodies are embalmed using formalin and stored within the mortuary. Freezers are utilised if fresh frozen material is required. If there is a requirement for prosected specimens and consent is in place, 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 type of tissue).

Anatomical examination by anatomy students takes place within the dissection rooms. Throughout the term, bodies are stored in the dissection room. There are 18 work stations within the main room and three in the smaller dissection room. The medical students undertake a dissection of a whole cadaver over the course of a year, with 7-8 students at each workstation. During dissection classes, students are supervised by teaching staff, technicians and demonstrators. Before undertaking any practicals, students are required to attend an introductory/ orientation session, which includes information about the rules and

regulations. They are also required to wear appropriate personal protective equipment (PPE). Any residual tissue removed during dissection is kept with the body then transferred to a waste container allocated only to the individual 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. If there is no permission for retained parts, these are reunited with the rest of the body prior to disposal.

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, the Bequeathal Coordinators and Technical Staff, an Anatomy Lecturer and the DI. 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 from storage to consent documentation.
- three potted specimens from the archive.
- five prosections stored in the anatomy teaching area store room.

For the prosections and potted specimens, a paper list, continuously updated by the establishment to track the location of parts was checked.
For each of the whole bodies, the consent documentation was reviewed, including any permissions for parts to be kept. There were no discrepancies found.

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

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	Although staff have received training in the requirements for obtaining valid and appropriate consent, records show that training was last carried out in 2013.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Although records show that audits have been carried out in 2016 and 2019, there is no documented schedule.	**Minor**
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.	The service road that funeral directors use to access the mortuary is in a poor condition. It has an uneven surface with cracks and pot holes. This presents a risk to the deceased, as well as to staff, as trolleys cannot be manoeuvred smoothly.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	Although the establishment confirms verbally with the deceased GP that the Medical Certificate of Cause of Death (MCCD) has been issued and signed, it is not formally recorded that the check has taken place. The DI is advised to consider including a way of documenting this check on bequeathal paperwork.
2.	GQ4(b)	The majority of the establishment's documents are in paper format. The DI is advised to consider whether document management could be strengthened; for example, by scanning in paperwork and taking advantage of electronic applications, such as databases.

3.	T1(f)	The contracted funeral director has recently changed and the Service Level Agreement (SLA) is currently in draft. The DI is advised to finalise this document and get it signed off by both parties.
4.	PFE2(c)	All of the temperature-monitored areas have external alarm and call-out systems. The DI is advised to challenge all alarm systems to ensure that, when temperature deviations are detected, the system operates successfully.
5.	PFE2(c)	Some of the potted specimens have low levels of fixative solution. The DI is advised to review the collection and ensure optimal storage conditions are maintained or restored so that integrity of the specimens is assured as far as possible.
6.	PFE2(d)	Fridge and freezer storage arrangements at the establishment are not critical as the majority of material is embalmed. Although they do have a contingency plan this is not formalised. The DI is advised to formalise the arrangements for storage failure.

Concluding comments

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the three 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.

Report sent to DI for factual accuracy: 28 August 2019

Report returned from DI: 06 September 2019

Final report issued: 12 September 2019

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: 25 August 2020

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.