Site visit inspection report on compliance with HTA minimum standards

UCL Ear Institute

HTA licensing number 12161

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **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.**

7 March 2017

Summary of inspection findings

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

Although the majority of the standards were met, three minor shortfalls were found in relation to governance and quality systems, risk assessments and disposal.

The HTA's regulatory requirements
The HTA must assure itself that the Designated Individual (DI), Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out under the licence held by UCL Ear Institute (the establishment) which includes the Royal National Throat Nose and Ear Hospital (RNTNEH), This was the second routine site visit inspection of the establishment by the HTA. The previous inspection took place in 2011.

The scope of inspection included a review of storage locations and the teaching lab at RNTNEH where all relevant material is stored. A review of governance documentation was also undertaken and formal interviews were conducted with staff working under the licence.

The DI under the licence is a consultant ENT Surgeon and Clinical Director for the RNTNEH. The Corporate Licence Holder (CLH) is the UCL Ear Institute. The CLH contact is the Interim Co-Director and Reader in Auditory Cell Biology for the Institute.

The establishment imports fresh frozen cadaver heads from the USA. The material is received a couple of days prior to the course and is stored only for the course duration. The establishment also stores an archived collection of temporal bone sections and related tissue and a collection of skulls imported from India that pre-date the Human Tissue Act 2004 (HT Act). In addition, they store material for research which is exempt from HTA licensing because it is for projects which have qualifying ethical approval.

A two-day rhinoplasty course is run annually for both international and UK trainee and established Ear, Nose and Throat (ENT) surgeons. All parts of the course are run and managed by an ENT surgeon and a registrar. Fresh frozen cadaveric heads are imported from Science Care in the USA for the course. The cadaveric heads are ordered through a purchase ordering system by the CPD Administrator or Admin Assistant. This is followed by the completion of a human tissue request form. All orders and request forms are reviewed and signed off by the Institute Manager or the Director of the Ear Institute. Science Care always confirm the orders by email. Each cadaver head is labelled with a unique donor identification number. The accompanying paperwork includes a statement outlining the informed consent that was given for the donation and a donor sheet that confirms the test results and low-risk status of the donor.

Deliveries of fresh frozen cadaver heads are arranged in advance and the reception area is in a secluded area at the rear of the building, with CCTV monitoring. The establishment is notified by the courier service about an hour before arrival and the cadaveric heads are delivered the Friday before the course begins (usually on the following Monday). Upon receipt, the facilities manager signs for the material, delivers it to the training lab at the RNTNEH and hands it over to the course leader. It is then checked, unpacked and put into a locked fridge for a period of thawing. The lab is alarmed and locked with swipe card access.

On the first day of the course, before starting any dissection, delegates are given a presentation about the code of conduct during the course (see Advice item 6). Approximately 8-10 cadaver heads are used, with two delegates assigned to each head. When tissue is removed during dissection, it is kept with the originating specimen for disposal. At the end of the first day, all specimens are put into locked fridges overnight. The training room is also locked. On day two, the course leader and registrar set up the course. Once the course is finished, they prepare the heads for disposal and these are then collected by the facilities manager and taken by the courier for disposal. Details of the disposal are recorded.

Since the rhinoplasty course is conducted only once each year, and the previous course ran in October 2016, there were no cadaveric heads in storage or use at the time of the inspection. However, for traceability audit purposes, the inspection team reviewed paperwork associated with the material from import to disposal. No anomalies were found. A traceability audit of the material that predates the HT Act was also undertaken and identified gaps in the audit trail (see Advice item 4).

Inspection findings

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

Compliance with HTA standards

Governance and quality systems

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	A two-day rhinoplasty course is run annually for both international and UK trainee and established Ear, Nose and Throat (ENT) surgeons. From formal interviews with staff, procedures appear to be in place for licensable activities. However, these are not documented. There are no Standard Operating Procedures (SOPs) for the cadaver heads imported from the USA used in the rhinoplasty course which relate to: • ordering of specimens • receipt • labelling • storage • relevant transport arrangements • cleaning and decontamination • disposal This shortfall needs to be resolved to the HTA's satisfaction prior to the next course being run. **See Advice item 1**	**Minor**

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	There are no risk assessments covering risks relating to premises, practices and procedures connected with licensed activities including: • loss or damage to the specimens • loss of traceability • receiving specimens without appropriate documentation • storage of anatomical specimens • transport of specimens to and from the establishment • security arrangements **See Advice item 5**	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue	The establishment does not have a documented disposal policy. **See Advice item 7**	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	In developing SOPs for material used for the rhinoplasty course, the DI is advised to include the following elements of review and document control: • revision history and version number • 'effective from' date • review date (at least every 3 years) • pagination • author and reviewer names
2.	GQ2	In advance of the next rhinoplasty course, the DI is advised to consider what audits should be carried out with respect to the specimens that will be received, stored, used and disposed of. Audits should be recorded and may include horizontal audits by staff involved in the process to ensure that SOPs accurately reflect actual practices and areas for improvement are identified.

		All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards. Audits can benefit from being undertaken by a person who is not normally involved in the activity which may provide more independent assessments.
3.	GQ2	The DI is advised to create a Quality Manual (QM). The QM should be accessible to all staff involved in licensable activities and provide a practical overview of the establishment's activities.
4.	GQ5	The DI is advised to compile a master inventory list of all the specimens in storage. This will result in more effective use of the available storage space and will facilitate speed of access in locating the specimens.
5.	GQ7	The DI should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. He should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining. Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident. By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.
6.		As seen at other establishments, the course leader for the rhinoplasty course is advised to consider developing a written code of conduct for delegates which reflects the requirements of the HT Act and Codes of Practice on Anatomical Examination. Delegates can sign to confirm they have read and understood the code of conduct before participating in the course. This can help to ensure that dignity of deceased is upheld.
7.	D1	The disposal policy should detail procedures for preparing the specimens for disposal and requirements for recording the details of disposal including the date, reason and method.

Concluding comments

Improvements need to be made in relation to overarching governance and quality systems. However, overall, the HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with legislation. As good practice, the DI under the licence meets with other DIs across UCL licenses to share information. The course leaders for the rhinoplasty course use feedback forms from delegates to review, develop and improve the course.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended time frames 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 21 March 2017

Report returned from DI: 29 March 2017

Final report issued: 30 March 2017

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: 20 October 2017

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Independent interpreters are available when appropriate • Information is available in suitable formats

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

- Standard operating procedures (SOPs) detail the consent process
- Evidence of suitable training of staff involved in seeking consent
- Records demonstrate up-to-date staff training
- 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

- Policies and procedures are in place, covering all licensable activities
- Appropriate risk management systems are in place
- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
• There is an identification system which assigns a unique code to each donation and to each of the products associated with it • An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom
GQ6 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transportation • Records of transportation and delivery • Records are kept of transfer agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure

from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.