Site visit inspection report on compliance with HTA minimum standards

Anatomy and Clinical Skills, Newcastle University

HTA licensing number 12148

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.**

25-27 May 2016

Summary of inspection findings

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

Although the HTA found that Anatomy and Clinical Skills, Newcastle University (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to HTA standards GQ5 and GQ7. Traceability held at the hub for some prosections transferred to the Queen's Campus satellite was incomplete in some cases, and no documented assessments of risk to human tissues had been carried out at one of the satellite sites, the Temporal Bone Laboratory.

Since the previous inspection, the post of DI has been taken over by another member of establishment staff, and Radio Frequency Identification tags have been introduced at the establishment hub site to aid traceability.

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

The HTA's regulatory requirements

The HTA must assure itself that the 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

The establishment comprises a hub facility, the Anatomy and Clinical Skills department at Newcastle University, and 3 satellite facilities at:

- Queen's Campus, Durham University
- Newcastle Surgical Training Centre, Freeman Hospital
- Temporal Bone Laboratory, James Cook University Hospital

The establishment is a major undergraduate teaching resource within both the Faculty of Medical Sciences at Newcastle University and the University of Durham, School for Health, at Queen's Campus, Stockton. In addition, the establishment provides postgraduate training facilities in surgical skills for the teaching and education of medical and other professionals at the Freeman Hospital and James Cook University Hospital sites.

The licensed premises at Newcastle University comprise a dissecting room, a continuing professional development (CPD) laboratory and an embalming and storage area. Adjacent to

these are an associated clinical skills laboratory, storage rooms, a museum room and technical support rooms.

The establishment accepts approximately 60 body donations each year, the majority being allocated for surgical training, with others being used in anatomical examination. The bequethal secretary and technical staff are involved in both the selection of those cases suitable for donation and subsequent checking of the validity of consent.

Each body received into the hub is assigned a unique accession number and a corresponding Radio Frequency Identification (RFID) tag is attached to the body. This tag is scanned to enter the body details into the establishment's database and subsequently scanned on movement between locations both within the hub and outside, for example to the Queen's Campus satellite, as well as recording release of the body for cremation. Prosections produced from a donated body are similarly tagged, scanned to link their RFID tags to the main body's details in the establishment's electronic database, facilitating traceability.

Bodies are preserved using a commercially available embalming process, which results in the body maintaining flexibility and a more lifelike appearance, which aids in differentiating the various anatomical features. Bodies and prosections are stored in monitored refrigerators which are alarmed locally and to switchboard.

Three or four donated bodies each year are supplied by the hub to its satellite facility at Queen's Campus, Stockton, where undergraduate medical and pharmacy students study anatomy during the first two years of their training at Durham University. As scanning is not currently possible within the Queens Campus facility, in addition to the RFID tag attached to the body by staff at the hub prior to transfer, staff at Queens Campus attach a further metal tag detailing a sequential number and year of receipt. Prosection details and identification numbers are logged into a database and are recorded in paper records. Each prosection produced from a donated body is tagged with a number linking it to that of the body and an RFID tag attached. The bodies used for anatomical dissection are stored on dissection tables within a restricted access dissection room, with prosections being stored within sealed containers within the same facility. Bodies and non-retained prosections are returned to the hub for disposal by cremation, and staff at the hub then scan the prosection RFIDs and link those prosections to the database records for the body itself, again to facilitate traceability.

The hub establishment also facilitates the supply of bodies to the Newcastle Surgical Training Centre (NSTC) at the Freeman Hospital. Bodies used for surgical training are not embalmed, but instead are frozen on site at the NSTC. When the bequethal secretary at the hub receives a telephone call relating to a potential donation, she considers whether it may be a suitable donation for transfer to the NSTC, deals with consent and traceability paperwork, and communicates with relatives as for donations to the Anatomy and Clinical Skills department. The donated body is then delivered directly to the NSTC by the establishment's contracted funeral director.

The NSTC accepts donations from other medical schools, but staff at the hub deal with the consent and other documentation in the same way as for bodies donated to the Anatomy and Clinical Skills department. Traceability is maintained by the use of names and dates of birth and the assigning of unique numbers, supplied by staff at the hub, to each donated body. NSTC accepts approximately 45 donations each year, for use in some 152 courses it runs, facilitating the training of between 800 to 1000 delegates each year.

The NSTC also uses fresh frozen body parts and, rarely, full bodies imported from a specialist supplier based in the USA, for specific training courses. Bodies and body parts are stored within monitored storage freezers, which are alarmed locally and externally to switchboard. Bodies and body parts are thawed in temperature controlled refrigerators prior to use in surgical training.

When bodies and body parts have been used for surgical skills training, staff at the NSTC arrange for cremation or incineration as appropriate.

Temporal bones prosected from bodies accepted for anatomical examination at the hub facility are used for training purposes by Ear, Nose and Throat speciality surgical trainees at the Temporal Bone Laboratory, James Cook University Hospital, Middlesbrough. Although embalmed, these prosections are stored within a locked freezer within a restricted access training laboratory. After use, the temporal bones are returned to the hub for disposal.

This was the second routine site inspection by the HTA, the previous inspection having taken place in 2011. In the interim period, the post of DI has been taken over by the medical school Director of Anatomy and Clinical Skills.

The scope of this inspection included a visual inspection of embalming, storage and dissection room facilities at the hub (the Anatomy and Clinical Skills department), the dissection and storage rooms at Queen's Campus, the storage and operating rooms at NSTC and the Temporal Bone Laboratory. The hub site also has a small collection of potted specimens, used in education. At the time of the inspection, the potted specimens had been moved from their display cases to facilitate setting up of examination areas for student clinical skill examinations. Accordingly, the HTA did not include the potted specimens in this inspection.

At each site, a review of relevant governance and record documentation was undertaken and key members of staff undertaking licensable activities were interviewed.

The review of each facility included a traceability audit:

- The identification tags of two bodies stored at Queen's Campus were noted and relevant records reviewed for the presence of consent documentation, transport records and details of any prosections made. The identification numbers of each prosection were noted, checked within the paper records and the prosections retrieved from storage and identification tags reviewed. No anomalies were found.
- A total of 11 prosections were located within the storage boxes, the numbers on identification tags reviewed and the records traced through to the paper records held by the establishment. Subsequently, records held at the hub were reviewed for presence of consent and traceability documentation.

  Minor discrepancies on the hub's traceability database were identified for four of the older prosections, which had been recorded as disposed of. This appeared to have arisen as a result of a change from a paper-based record system to the database system at the hub. For two of those prosections, evidence of consent for retention was subsequently located.
- Identification details of the four temporal bones held at the Temporal Bone Laboratory were recorded and compared against the paper records held by the establishment. No discrepancies were found, though the age of the specimens again meant that it was not possible to locate related consent documentation in the database at the hub.
- Identification details of two bodies in storage at the NSTC were recorded and the corresponding consent and related transport traceability documents reviewed. The details held within the establishment database were also reviewed. Records held at the hub were reviewed for presence of consent and traceability. No anomalies were found.
- Similarly, two body parts imported from the supplier in the USA were located in storage and the corresponding database and paper records reviewed. No anomalies were found.

- At the hub site, details of two bodies were noted on the white board, the corresponding cadavers located in store and the RFID tag numbers noted and checked against paper and electronic database records for presence of consent records. The RFIDs of four prosections were noted and again checked in the database for the accuracy of recorded location details and the presence of the related consents. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The database records held by the hub inaccurately recorded the disposal of four of the prosections audited at the Queen's Campus site, meaning that there was a loss of traceability. Traceability records relating to the four prosections held at the Temporal Bone Laboratory were not found on the database at the hub. Traceability records held at each of the satellites allowed the prosections to be located easily.	**Minor**
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	There were no documented risk assessments of risks associated with licensed activities carried out at the Temporal Bone Laboratory. By carrying out and documenting such risk assessments, the DI will identify factors which may help to mitigate risks such as absence of appropriate consent, loss of traceability, security risks, and potential for specimen damage in the event of equipment failure.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2	The DI is advised to review the documentation providing information to potential donors and their next of kin to ensure that timescales mentioned in relation to retention times for prosections reflect the period of use relevant to activities for which prosections are used. The DI is further advised to ensure that the wording of the information to next of kin is amended to refer to the body of their relative, rather than state “your body”.
2.	GQ1	The DI is advised to update the Standard Operating Procedure (SOP) in use at the Queen’s Campus, detailing how to test and mute the alarm, to specify the interval between alarm tests. The DI is advised to develop the “Use of Tissue” document in use at the Temporal Bone Laboratory, which is not a controlled document, into an SOP governing receipt, storage and use of prosections, as well as clarifying how use is recorded. The HTA noted that there had been some confusion in how trainees recorded use of the specimens within the log book and record sheets and definitive guidance will help to ensure clarity in recording use and help to maintain traceability. The DI is advised to modify the SOP in use at the NSTC for receipt of bodies into the establishment or to develop a separate SOP documenting how imported body parts are received and recorded within the unit. The DI is advised to review the Code of Conduct document used within the NSTC to ensure that those signing are acknowledging the need to comply with all requirements of the Code of Conduct and not only those relating to liability for transmission of disease. The DI is advised to ensure that the guidance document used within the Anatomy and Clinical Skills department detailing how the alarm should be muted following it sounding is document controlled, or appended to a document controlled SOP. The DI is advised to ensure that all Persons Designate (PDs) attend meetings dealing with the licensed activities. The HTA notes that work pressures impede the ability of one of the PDs to attend. If necessary, the DI should consider the use of teleconferencing. Meetings of PDs help to cascade learning and provide a forum for discussion of HTA relevant topics.
3.	GQ2	The HTA notes that reciprocal audits against HTA standards are carried out by staff at each centre and these include review of relevant SOPs. The DI is advised to ensure that such audits also include elements of vertical audit of traceability and horizontal audits of legibility and accuracy of documentation at each centre. The DI is advised to ensure that the audit of traceability carried out at NSTC includes traceability of imported body parts as well as bodies. By amending the audit procedures, the DI will help to identify any systemic issues affecting traceability and documentation.
4.	GQ4	The DI is advised to ensure that the record of prosections recorded on donor body maps is made in pen. Currently records are made in pencil which negates the ability to track amendments accurately. The DI is advised to audit the records and prosections held at Queen’s Campus against the records held in the database at the hub. The HTA identified some discrepancies in the records held at the hub when compared to

		those held at Queen's Campus, and by carrying out such an audit the DI will be able to identify if this is more widespread. Following the audit, if any existing specimens are found to be recorded within the database as disposed of, the DI is advised to assess, taking into account the terms of any existing consents, whether the database records should be amended, or whether prosections should be disposed of. The DI is advised to introduce an audit of the electronic traceability records resulting from scanning in of RFID tags, to identify any issues arising from the use of the system, which may inform procedures if rolled out to other sites.
5.	GQ5	The DI is advised to consider retrospectively tagging prosections held at the Temporal Bone Laboratory with RFID tags to help facilitate traceability within the database held at the hub on their return for disposal. While traceability at the Temporal Bone Laboratory was demonstrated, confusion as to how records are maintained within the laboratory, using a log book and loose leaf files, made the process of demonstration more difficult than needed.
6.	GQ7	The HTA noted that risk assessments at the Queen's Campus, the NSTC and the Anatomy and Clinical Skills centre included a variety of 'regulatory risks' in addition to Health and Safety risks. The DI is advised to review the suite of risk assessments undertaken to ensure that all relevant risks are considered consistently across all sites.
7.	GQ7, PFE3	The HTA notes that embalmed prosections are held within a locked freezer within the Temporal Bone Laboratory, primarily as a means of ensuring secure storage. As storage within a freezer introduces risk of damage to the prosections in the event of equipment failure, the DI is advised to risk assess this arrangement and to develop a process whereby the function of the freezer is regularly monitored and recorded. Results of this monitoring should be trend assessed to aid identification of potential equipment failure.

Concluding comments

The HTA saw various examples of good practice during the inspection.

- SOPs are clear and easy to read, having been created in a visual, diagrammatic format rather than being text-based. All SOPs are discussed and reviewed on a rolling basis during meetings of staff carrying out licensable activities, aiding the sharing of ideas.

- The establishment uses a "body-map" diagram to record where prosections have been derived from donated bodies. Technical staff review the accuracy of these on return of bodies for cremation.

- Staff at the hub have introduced the use of RFID tags to aid traceability of bodies and body parts, including scanning into and out of the department, for example when on loan or sent to one of the satellites.

- There appear to be good working relationships and communications between clerical, clinical and technical staff working at the various sites, which aids the sharing of ideas and learning.

- On the change of contractor used for disposal of clinical and anatomical waste within the University, staff from the establishment estates department visited the preferred contractor to assure themselves of the suitability of the processes used. This visit identified an area where the robustness of traceability procedures could be improved and change was effected.

There are areas of practice that require improvement, resulting in two minor shortfalls. The HTA has given advice to the DI with respect to some elements of documentation, risk assessment and audit.

The HTA requires that the DI addresses the shortfall 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 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 17 June 2016

Report returned from DI: 28 June 2016

Final report issued: 28 June 2016

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: 06 October 2016

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.