Site visit inspection report on compliance with HTA minimum standards

University of Oxford, Medical Sciences Division,
Medical Sciences Teaching Centre

HTA licensing number 12178

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.**

18 September 2014

Summary of inspection findings

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

Although the HTA found that the University of Oxford, Medical Sciences Division, Medical Sciences Teaching Centre (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to internal audit and governance documentation.

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 Designated Individual, 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 by the University of Oxford Medical Sciences Teaching Centre (MSTC). The establishment has been licensed by the HTA since July 2007 and has been inspected on one previous occasion. This report describes the second routine site visit inspection of the establishment, which took place on 18 September 2014.

The MSTC was opened in 2002 and is located adjacent to the Sir William Dunn School of Pathology. The MSTC receives donated bodies directly for the purpose of anatomical examination and training. The bequeathal process is undertaken by a core team of staff at the establishment according to well-defined procedures. All staff involved in the bequeathal process have received specific training to help ensure that valid consent for body donation is given and that it is appropriately documented.

Once receipted into the MSTC, the majority of bodies are embalmed. Embalmed bodies are stored within a dedicated mortuary facility, located within the MSTC, which has refrigerated space for 20 bodies. A further 10 spaces are available for bodies requiring frozen storage. The latter are used primarily for surgical training purposes, although they may be embalmed after a period of frozen storage if needed. All fridges and freezers within the mortuary are temperature controlled and alarmed. Once dissected, embalmed body parts are stored within the dissection room which is situated adjacent to the mortuary. Potted specimens and

skeletal remains, including full skeletons and disarticulated bones, are stored within the mortuary and dissection room, as well as in several other locations within MSTC. At the time of the inspection, the mortuary was staffed by two permanent members of staff who also play a role in the oversight of the specimens held elsewhere within the MSTC.

Donated bodies and specimens are used within the MSTC for the purpose of education and training of undergraduate and postgraduate students enrolled on courses within the university. The teaching facilities are also used for surgical skills training, as well for a variety of external courses that are organised by the establishment. In each case, access to the mortuary and dissection room is restricted and carefully controlled. All users of the facility must undergo a well-defined induction process, after which they are supervised at all times by permanent members of staff. Records of people attending courses and entering the facility are retained.

The inspection included interviews with key members of staff working under the licence, including the Emeritus Professor of Human Anatomy, who was also the Designated Individual (DI) at the time of the inspection, the Mortuary Supervisor and the Mortuary Technician. The inspection team also met with the University's Director of Human Anatomy who had submitted an application to take on the role of DI prior to the inspection. A review of documentation relevant to the establishment's activities and a visual inspection of the premises where licensable activities are carried out were also conducted as part of the inspection.

An audit of two bodies and six specimens was performed during the inspection. Storage locations were cross-checked with paper and electronic records and donor files were reviewed to ensure that they contained all relevant documentation, including consent forms. The specimens chosen for the audit were representative of the range of relevant material stored under the licence and included examples of body parts, potted specimens and skeletal remains. As a result of this, a variety of storage arrangements were also included in the audit, including storage in 4^{o}C fridges and storage at room temperature of both wet and dry specimens. No discrepancies were found. Additional records associated with the establishment's holdings, notably the loans booklet, were also reviewed. This exercise identified a number of minor inconsistencies in working practices and areas for possible future development which are commented on in the sections below.

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

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.	Although the establishment has a wide range of SOPs dealing with the storage and use of bodies and body parts, not all aspects of the work that takes place under the authority of the establishment's HTA licence are supported by ratified, documented procedures. For example, the establishment's procedures for embalming frozen bodies after a defined period in storage are not documented, and the procedures for the storage and audit of skeletal remains lack sufficient detail to ensure traceability. The establishment's contingency procedures associated with fridge/freezer failure are not adequately documented, nor are the procedures for contacting key members of staff should the fridges/freezers go into alarm. Furthermore, the SOP that deals with the receipt of bodies (SOP05) does not capture all of the donor identification checks that are performed at the point of receipt, such as cross-checks with the information recorded on the HTA(A)7 form. Additional guidance on the establishment's policies and procedures is given in the Advice section below.	**Minor**
GQ2 There is a documented system of quality management and audit.	Although the establishment conducts annual audits of 'wet' holdings, these do not encompass the specimens held in the neuroanatomy department or the skeletal specimens held throughout the MSTC. Furthermore, the establishment does not conduct regular audits of records to check for completeness, legibility and accuracy. During the inspection it was noted that the loans booklet contained several entries that had not been completed accurately or in line with the establishment's procedures. The records also suggested that several specimens remained on loan beyond the stated 'return by' date without evidence of this having been reviewed or authorised.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to update the establishment's documentation to include references to the HTA's current Codes of Practice where relevant.
2.	GQ1	The DI is advised to formalise the establishment's procedures for contacting families in the event that a completed HTA(A)1 form is not received. This should include clear guidance on appropriate timeframes for follow-up calls or letters, and an escalation plan to cover those occasions when completed forms cannot be obtained.
3.	GQ1	The DI is advised to consider additional ways of identifying bodies with the same or similar names to further mitigate the risk of a loss of traceability or the release of the wrong body for burial or cremation. This could include, for example, the addition of visual reminders in written records, on fridge/freezer doors, or on body shrouds.
4.	GQ1	The DI is advised to update the SOP dealing with the embalming of bodies to remove reference to the use of a face mask during the procedure. This will bring the SOP in line with current working practices.
5.	GQ2	Although the establishment has made a number of changes to the format of SOPs in response to advice that was given during the last inspection, the DI is advised to consider inclusion of 'Author', 'Reviewed by' and 'Review by date' fields on all controlled documents. The DI is also advised to consider whether the inclusion of signature log sheets in SOPs and the creation of a circulation list for printed procedures would further strengthen the establishment's document control system.
6.	GQ7	The DI is advised to review the format and content of the risk assessment relating to 'donor operations'. In particular, the DI should consider creating separate risk assessments for the acceptance, care, storage, use and disposal of donated material as this will facilitate a more comprehensive review of the risks and existing control measures associated with each of these activities.
7.	PFE2	The DI is advised to document the routine cleaning and decontamination of the mortuary and dissecting room. This will help ensure that this activity continues to be carried out in accordance with the establishment's procedures and facilitate appropriate audit. The DI is also advised to keep records of the weekly checks for mould that are conducted by staff in the mortuary and dissection room. This will help to identify any issues relating to the establishment's storage equipment or working practices that have the potential to impact on the quality and integrity of bodies and specimens.
8.	PFE3	The DI is advised to review the establishment's SOPs relating to the storage of bodies and body parts to ensure that the temperature limits of fridges and freezers during routine operation are consistently and accurately documented. This will help ensure that excursions from agreed limits are identified, logged and appropriately investigated.
9.	PFE3	At the time of the inspection the establishment was in the process of linking the

		fridge/freezer alarm system to the security switchboard to help ensure the safe storage of bodies. Once this work has been completed, the DI is advised to put a documented procedure in place to regularly check that the system, including staff notification and call-out, continues to work as intended. The establishment was also in the process of formally reviewing the on-going suitability of the primary body storage facility within the mortuary as a result of a warped frame which has affected the seals within the units. Although the inspection team saw no evidence that the warping of the frame had affected the ability of the fridges/freezers to maintain a consistent storage temperature, the consequent build-up of condensation and ice within the units could lead to a number of issues such as the build up of mould. The DI is therefore advised to complete this formal review exercise at the earliest opportunity with a view to replacing or repairing the units as appropriate. In the meantime, the DI is advised to complete a formal risk assessment for the on-going use of the primary body store. As part of this exercise, the DI is advised to review the use of wood within the mortuary fridges due to the difficulty of cleaning porous surfaces.
10.	PFE4	The DI is advised to put in place a formal agreement with the Funeral Director responsible for movement of bodies to and from the mortuary. This will help ensure that the roles and responsibilities of each party, and agreed-upon working practices, are clearly defined.
11.	General	The DI is advised to consider nominating a Person Designated for the mortuary and dissection room to assist in the further development and implementation of the systems needed to ensure ongoing compliance with the requirements of the Human Tissue Act.

Concluding comments

The HTA saw numerous examples of good practice during the course of the inspection.

The bequeathal process is well-thought out and staff involved in this activity are supported by a clear and comprehensive set of documents, forms and procedures. The mortuary and dissection room are similarly well-managed with a good level of attention having been given to ensuring the safe and dignified storage of bodies and body parts within the MSTC. The establishment has implemented a number of robust procedures to ensure that users of the facility are aware of their responsibilities whilst participating in courses or training, which measures such as swipe card access and close supervision help to reinforce.

Staff at the establishment are very engaged in their work and throughout the organisation there was a clear commitment to continuous improvement. This was evidenced, in part, by the steps the establishment has taken to review the ongoing suitability of the storage facility and its alarm system, as well as the training initiatives that have been implemented that make use of expertise in local hospitals.

Two areas of practice were identified during the inspection that require improvement, both resulting in minor shortfalls. These relate to the scope of the establishment's internal audits and its formal, documented procedures. The HTA has also given advice to the Designated Individual with respect to a number of the establishment's procedures, documents and working practices with a view to helping the organization further develop its working practices.

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 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: 14 October 2014

Report returned from DI: 22 October 2014

Final report issued: 22 October 2014

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: 18 March 2015

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.