Site visit inspection report on compliance with HTA minimum standards

Minimal Access Therapy Training Unit

HTA licensing number 12547

Licensed under the Human Tissue Act 2004 for the

- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

29 June 2016

Summary of inspection findings

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

Although the HTA found that the Minimal Access Therapy Training Unit (the establishment) had met the majority of the HTA standards, five minor shortfalls were found with regard to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. They were in relation to an absence of: (i) governance meetings; (ii) a formalised competence training programme; (iii) consistent reporting and follow up of incidents; (iv) risk assessments; and (v) continuous temperature monitoring of refrigerators and freezers. Advice has been given relating to the GQS, PFE and Disposal standards, as well as to licence management.

The HTA's regulatory requirements

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

The statutory duties of the DI 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 licenses 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 Minimal Access Therapy Training Unit (MATTU, the establishment). MATTU was issued an HTA licence in June 2009 and was last inspected in October 2010. The current inspection was a routine site visit to assess whether the establishment is continuing to meet the HTA's standards.

The establishment is licensed under the Human Tissue Act 2004 (HT Act) for the storage of the body of a deceased person, or relevant material which has come from a human body, for use for a scheduled purpose. In this case, relevant material from deceased donors is stored for education or training relating to human health. The DI is the MATTU Business Manager, the Corporate LH (CLH) is currently MATTU, the licensed establishment (*see Advice item 1*), and the CLH Contact (CLHC) is a Director of MATTU. There are two Persons Designated (PDs) on the licence, both orthopaedic surgeons.

MATTU imports, stores and uses fresh frozen upper and lower limbs, and heads, for surgical training, primarily foot, ankle, hand and wrist, and ear, nose and throat surgery. There are approximately three courses using human tissue each year. The course delegates (limited to 20) undertake the training in the skills laboratory based at MATTU, in the Postgraduate Medical School of the University of Surrey. The governance arrangements of MATTU fall under the remit of the University of Surrey's Health and Safety Governance structure although all the staff working under the licence are employees of the Royal Surrey County Hospital NHS Foundation Trust (*see Advice item 4*).

The cadaveric specimens are purchased from an American Association of Tissue Banks

(AATB) - accredited organisation in the USA. There is a Material Transfer Agreement (MTA) with this organisation but it is out of date (*see Advice item 15*). The agreement covers donor selection, consent from donors (or their next of kin), donor testing, courier transport to the establishment and full traceability. Donor identity is kept, confidentially, by the US organisation, which gives specimens a unique tissue identifier (*see Advice item 7*).

The exterior of the Postgraduate Medical School is monitored by closed-circuit television (CCTV) and entry is controlled by swipe card. The skills laboratory is secured with both swipe card and key lock access. There is no clear demarcation between the changing area and the skills laboratory (*see Advice item 14*).

Air quality within the skills laboratory is monitored by the University Estates and Facilities Management Department (*see Advice item 13*). The laboratory is clean and well maintained and has 12 tables for training. Specimens are fixed onto the tables to prevent mix ups. Surgical equipment, consumables and reagents are provided by the course organisers and used reagents are taken away at the end of the course in sealed containers. The laboratory is routinely jet washed and decontaminated at the end of each course.

Trainees are provided with personal protective equipment. The course participants are asked to read a Code of Conduct before the course although confirmation that delegates understand and agree to it is not sought or recorded (*see Advice item 12*).

Cadaveric specimens are kept double-wrapped in a locked, temperature-alarmed -20°C freezer in the store room before being transferred to a locked 4°C refrigerator for overnight storage before use in the skills laboratory. A separate locked -20°C freezer is used for the occasional storage of animal tissue and as a contingency. The refrigerator is cleaned between courses and the store room is regularly cleaned. Although there are procedures which cover specimen receipt, storage, use or disposal there is no system for identifying, recording and following up any adverse events which may occur during this process (*see Shortfall under GQ6*). There are also deficiencies in the storage temperature monitoring system (*see Shortfall under PFE3*).

The establishment has a policy indicating that cadaveric specimens should be retained for a maximum storage time of 12 months. Specimens which have exceeded their expiry date, or excess tissue from training courses, are incinerated appropriately under agreement (*see Advice items 17 and 18*).

Paper records are kept in locked cabinets in the MATTU office adjacent to the skills laboratory. Electronic records are held securely (*see Advice items 8 and 9*).

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection report, compliance update information and reported enquiries. The inspection included a visual inspection of the lecture theatre, changing area, skills laboratory, store room and goods receipt area. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the DI, CLHC and the two PDs. Several audits of traceability were carried out.

Four specimens were selected from the -20°C freezer and labelling details were compared to paper and electronic records. A separate specimen was traced from the paper and electronic records to the freezer. Records checked included date of receipt, date the specimens were placed in the freezer, date when they were moved to the refrigerator and date when used in the training course.

A further specimen was traced from receipt to storage use and disposal. No discrepancies were noted in any of the audits.

Inspection findings

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

The CLH is currently MATTU (the licensed establishment) and this is not appropriate (*see Advice item 1*).

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.	There are no regular governance meetings where the DI, CLHC and PDs can discuss issues relating to HTA-licensed activities. In the context of the other identified shortfalls, this is an area that will help to strengthen governance arrangements. *See Advice item 3.*	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	There is no formal and recorded competence training for staff involved in receiving and handling cadaveric specimens. This is especially important for situations when the DI is not available. *See Advice item 6.*	**Minor**
GQ6 There are systems to ensure that all adverse events are investigated promptly.	During the inspection it was noted that several adverse events had occurred but these had not been formally recorded or followed up. These included: - Damage to a delivery box containing specimens. - Incorrect ID number on a delivery bag containing specimens. - Security breach by catering staff entering the establishment without authorisation. There is no system for identifying, recording and following up adverse events associated with specimen receipt, storage, use or disposal. *See Advice item 10*.	**Minor**
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	There are health and safety risk assessments but there are no risk assessments covering HTA-licensed activities. *See Advice item 11.*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	During the inspection it was noted that temperatures of the refrigerator and freezers are recorded manually by staff on a daily basis during the working week. There is no temperature monitoring at weekends or during vacation periods. The refrigerator and freezers have audible alarms but the set range for the alarm system is not documented and the audible alarm system is not routinely tested. There is no documented procedure indicating steps to be taken if the audible alarms sound. There is no continuous temperature monitoring system of the storage facilities to ensure the dignity of the deceased. The establishment has not risk assessed the current arrangements for monitoring temperatures and the effects that storage temperature deviations would have on the dignity of the deceased.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The University of Surrey owns the building and is responsible for health and safety issues and security procedures. The DI should ensure that the CLH is changed from MATTU to the University of Surrey.
2.	GQ1	There is inconsistency in the current format of policies and standard operating procedures (SOP)s. The DI is advised to consider including the following, to create a more robust system of document control: • document identification number • document revision history and version number • 'effective from' date • review date (at least every three years) • pagination • author and reviewer names.
3.	GQ1	In other establishments, governance meetings cover items such as standardisation of documents, changes to SOPs, audits and their findings, competence and regulatory training, management of incidents, risk assessments, the setting up of agreements with other establishments, and the dissemination of national and local information relevant to activities in the anatomy sector (this may be covered in HTA e-newsletter items).

		The DI should ensure that the meetings are minuted and that actions are noted and followed up. Documented minutes should be distributed to all relevant staff.
4.	GQ1	The DI may wish to consider taking part in University Health and Safety Committee meetings to inform others of matters relating to the HTA licence.
5.	GQ1	The DI may wish to consider setting up meetings with local DIs at the Royal Surrey County Hospital (PM licence) and University of Surrey (Research licence) to share information and experience with them and their PDs. This may help facilitate learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
6.	GQ3	The DI should consider setting up a training matrix for each staff member to record competence in all procedures. Training should include: the familiarity with SOPs and risk assessments, and the reporting process for incidents.
7.	GQ4	The DI should consider incorporating an audit of a selection of donor consent forms provider by the US supplier to ensure that valid and appropriate consent is in place for donations.
8.	GQ4	The DI may wish to consider using a spreadsheet to record the full traceability of specimens from delivery to storage, use or disposal. This will assist in audits and will identify any discrepancies.
9.	GQ4	The DI may wish to consider backing up electronic records on a server rather than a memory stick to ensure secure record retention.
10.	GQ6	All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis. The DI should ensure that staff are aware of incidents relating to human tissue. These include: • specimen loss • loss of specimen integrity (e.g. broken packaging) • missing, incomplete or incorrect documentation • refrigerator and freezer temperature warming or breakdown • incorrect disposal • breach of security.
11.	GQ7	As well as health and safety issues, the DI should also assess risks associated with licensed activities. These include: • loss of or damage to specimens • loss of traceability • receiving specimens without appropriate documentation • storage of specimens and contingency arrangements • transport of specimens to the establishment • disposal arrangements • security arrangements. Risk assessments should be reviewed regularly and and after changes to key

		procedures. They should be made available to all staff undertaking licensed activities.
12.	PFE1	The DI should ensure that all course delegates sign that they have read, understand and agree to the Code of Conduct.
13.	PFE1	The DI should ensure that copies of air quality maintenance reports are kept up to date by keeping copies in MATTU or obtaining easy access to them.
14.	PFE2	To reduce cross-contamination into clean areas, the DI should ensure that there is clear demarcation of the changing area and the skills laboratory.
15.	PFE4	The DI should review the terms of the MTA with the US supplier of specimens and ensure that they are in accordance with the HTA policy on the import of fresh frozen bodies and body parts: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyontheimportoffreshfrozenbodiesandbodyparts.cfm The DI should also ensure that the MTA is signed and is up to date.
16.	PFE5	The DI should ensure that there is a documented contingency plan in the event of refrigerator breakdown.
17.	D1	The DI should ensure that the contract with the disposal company is signed and is up to date.
18.	D2	The DI should ensure that the reason for disposal is recorded and that this change in practice is included in the appropriate SOP(s).

Concluding comments

The skills laboratory and lecture theatre are in a modern, clean, purpose built and secure facility.

There are a number of areas of practice that require improvement, including five minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality Systems, Premises, Facilities and Equipment and Disposal standards, as well as to licence management.

The HTA requires that the DI 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: 26 July 2016

Report returned from DI: 04 August 2016

Final report issued: 01 September 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: 10 May 2017

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. 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

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 inspection.

   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.