Site visit inspection report on compliance with HTA licensing standards

Evelyn Cambridge Surgical Training Centre

HTA licensing number 12603

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.**

4, 5 July 2017

Summary of inspection findings

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

Although the HTA found that Evelyn Cambridge Surgical Training Centre had met the majority of the HTA's licensing standards, one shortfall was found in relation to a lack of documented audits (HTA standard GQ2(b)).

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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

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

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

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

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

HTA inspection reports are published on the HTA's website.

Background to the establishment

Evelyn Cambridge Surgical Training Centre (ECSTC), previously known as Cambridge Surgical Training and Research Centre (CAMSTARC), has been licensed by the HTA since June 2013. The centre provides advanced surgical training to medical professionals and clinicians from around the world, including training in minimally invasive surgery, microsurgery and open surgery. The establishment imports fresh frozen cadaveric material from two profit and one non-profit organisations in the United States of America (USA) for surgical training courses. The Designated Individual (DI) and the Corporate Licence Holder contact (CLHc) visited two organisations in 2013 to review their consent and ethical standards, and to ensure their donation and procurement processes are undertaken to a satisfactory standard, before entering into a formal agreement with them. A third supplier in the USA was visited in 2016 by the DI. The establishment accepts only material that has been donated by people who gave their consent while alive.

The establishment has grown rapidly, from running five courses in 2013 to a proposed 68 courses in 2017. Currently, the establishment has a hub and satellite arrangement but is looking to centralise activity at one site in the next three to five years. The ECSTC hub is located in Melbourn, near Cambridge, with a satellite site at Addenbroooke's Hospital, Cambridge.

Description of inspection activities undertaken

This report describes the second site visit inspection of the establishment since it was first inspected in 2013. The inspection comprised: a visual inspection of both the hub and satellite premises; interviews with the DI, the Senior Technical Manager, Senior Technical Assistant, Technical Assistant, Technician (satellite) and the Director of Operations for ECSTC, and; a thorough document review of all policies and procedures relating to the licensed activity. Receipt and disposal procedures were inspected and traceability audits were conducted.

The hub site (Melbourn)

The hub site stores a large amount of relevant material and the majority of courses take place at this site. There is a large seminar room, which holds up to 50 people, where delegates are briefed and receive introductory training prior to entering the laboratory. Delegates receive a Code of Conduct electronically prior to the course and are reminded of this in the briefing. The Code of Conduct is available in all languages from the delegates' countries.

The visual inspection at the hub comprised of the seminar room, the delegate changing facilities, the preparation room, the administration office where records are stored, the sluice room, the storage areas where cadaveric tissue is stored and the surgical training laboratory where courses are conducted. Access to the laboratory is by swipe card and keypad access

only and the doors are alarmed, with four individuals having unrestricted access to this area. The building has 24-hour security guards and CCTV surveillance; all entry to the building, including to the ECSTC by the delegates, must be through the main reception area. All doors within ECSTC have dual locks and only four people have access to the master key.

The establishment employs administrative staff who maintain all documentation pertaining to the courses, and technical staff, who are responsible for receiving the fresh frozen tissue and ensuring surgical instruments used in the training courses are decontaminated and cleaned. All technical staff and the DI can be responsible for receiving imported fresh frozen material on a designated day and at an agreed time. On receipt of a delivery, the establishment immediately assigns a unique identifier to each specimen. The unique identifier is a sequential number, which includes the year and is the internal reference that appears in the specimen register and on the electronic database. The specimens are received with accompanying paper work containing limited demographics, brief medical history and serology results to confirm tests performed on the donor for transmissible diseases. A plastic coloured tag containing the unique identifier, is embedded into each specimen. By tagging the material in this manner, each specimen is identifiable without unwrapping the external packaging, maintaining the integrity of the tissue.

There are two storage areas at the hub, one room contains two mortuary freezers and three chest freezers. The room itself is temperature monitored to allow appropriate thawing of specimens prior to a course. The second storage area is in the surgical skills laboratory, which contains two freezers and two fridges. All storage areas are temperature-monitored according to a pre-determined range. If a storage area falls outside this range, the DI is notified by text and can access the system remotely. Temperature records are reviewed for trends and alarms are routinely tested. The establishment has Grade 3 military destruction of all confidential documentation on site. Specimens for disposal are collected by SRCL, healthcare waste specialist company, at an agreed day and time and the site of incineration is inspected annually by the DI.

The surgical training laboratory consists of ten stations, with adjustable half-length tables, that allow two to three delegates to work at each station. It also contains three image intensifiers that allow x-ray of specimens and lead gowns and protectors are provided with appropriate signage in place. There are audio-visual facilities, with fitted ceiling cameras, that can be transmitted to screens in the seminar room. The Code of Conduct and Local Rules for Radiation are displayed in the laboratory.

Traceability audits were carried out on four specimens in storage and one that had been disposed of. Corresponding documents, data logs, specimen location and disposal records were checked. No anomalies were found.

The satellite site

The satellite contains significantly less relevant material than the hub, conducts fewer courses with smaller numbers of delegates, focuses on microsurgery and primarily stores cadaveric heads. The visual inspection at the satellite site included the reception area of the Cambridge Microsurgery Skills Laboratory, specimen storage room and surgical training laboratory. The satellite site is managed by a Person Designated (PD) on the licence.

There is keypad access to the main reception area and swipe card access to the training laboratory. The keypad access code is changed every couple of months. There are ten sit down stations and delegates are given all appropriate PPE. The PD of the satellite solely oversees the specimens on delivery, which can be planned up to 12 months in advance. Specimens are assigned a unique identifier on receipt, as at the hub site and are stored in a temperature monitored chest freezer. The manually recorded temperature log is reviewed for trends and is soon to be connected with the monitoring system at ECSTC. The same PD takes the specimens by hand to the incinerator on the Addenbrooke's Hospital site for disposal, at a pre-scheduled time and attended by witnesses. In the absence of the PD at the satellite site, a technician is given authority to receive specimens and place them in storage pending the return of the PD. Disposal is only undertaken by the PD and arrangements are made to achieve this.

Records and documentation pertaining to the specimens are kept in a locked office. A fire safe locker has been ordered by the establishment where they will be stored in future. A traceability audit was undertaken on two cadaveric heads in storage. Corresponding documents, data logs, specimen location and disposal records were checked. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

GQ2 There is a documented system of audit.		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	Although the establishment conducts regular 'stock check' audits of specimens, these audits are not documented or shared for future learning. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address this shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1 (a)	The DI is advised to review several SOPs for consistency. There are two separate SOPs (Receipt of Human Tissue and Receipt of Specimen) that both reference the satellite and do not have the same information regarding receipt of material there. The DI is advised to amend the incorrect document or have a separate document for receipt of material for the hub and a separate document for receipt at the satellite.
2.	GQ1 (a)	The DI is advised to include a reference to 'Receipt of Tissue' and/or Receipt of Specimen' SOPs in the Transport SOP. This is to ensure that no vital steps are missed on receipt of material at the establishment.
3.	GQ4 (a)	The DI is advised to amend the SOP for creation and disposal of records in line with changes within the establishment, as discussed on inspection.

Concluding comments

The establishment was found to have met the majority of HTA's licensing standards, with one minor shortfall that was corrected by the time of the final report.

A number of strengths and areas of good practice were observed during the inspection.

In terms of strengths:

- The premises and facilities provided by the establishment are extremely secure and well maintained

- The establishment has succeeded in providing a near 'real life' theatre experience for delegates within the surgical laboratory. All specimens are draped on adjustable tables, like they would be in an operating theatre. Free movement of limbs is achieved due to a specialised engineered design, developed by the DI, using clamps and blocks. Full scrub facilities are provided and many technical staff have previously worked in theatres and respond to surgical trainees like they would in theatre, all adding to the overall experience

- The establishment is supported by a highly specialised and dedicated team, who work well together, with a high level of DI engagement; all have the dignity of the deceased as one of their core values.

In terms of good practices:

- The DI has visited their suppliers in the USA and reported back to the establishment to confirm that they comply with their desired consent and ethical standards for the import of specimens;

- The DI has conducted research on the optimum time to receive imported specimens by the establishment in order to be ready for use, while maintaining the integrity of the tissue;

- A large number of SOPs and policies begin with an outline of the HT Act, the HTA and the responsibility of the DI, which is a useful reminder to staff;

- The DI visits the tissue disposal company annually to assure the establishment that disposal is being conducted in accordance with the HTA Codes of Practice;

- The DI personally gives specific training - including a presentation - to all new members of staff working under the licence, about the HT Act and the HTA's regulatory requirements.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 24/07/17

Report returned from DI: 24/07/17

Final report issued: 24/07/17

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: 24 July 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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensable activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing

these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly. c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of when and where the bodies. or tissue were acquired, the consent obtained, the uses to which any material was put, when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. **Major shortfall:**

   A non-critical shortfall that:

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

   or

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

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

3. **Minor shortfall:**

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

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

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

Follow up actions

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

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

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

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