Site visit inspection report on compliance with HTA minimum standards

Cambridge Surgical Teaching and Research 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.**

5 September 2013

Summary of inspection findings

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

Although the HTA found that Cambridge Surgical Teaching and Research Centre had met the majority of the HTA standards, a minor shortfall was found in relation risk assessments (HTA standard GQ7).

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 describes the first site visit inspection of Cambridge Surgical and Research Training Centre (CAMSTRAC) since it was first licensed by the HTA on 11 June 2013. This was a routine inspection. CAMSTRAC imports fresh frozen body parts, from a non-profit organisation in the USA, for surgical training courses. Prior to applying for the licence, the Designated Individual (DI) and Corporate Licence Holder contact (CLHc) visited the organisation in the USA to ensure that the donation and procurement of body parts was undertaken to satisfactory ethical and consent standards before entering into a formal agreement. CAMSTRAC have a formal agreement with the USA organisation, which confirms that all specimens received are with the consent from the donor (see advice and guidance item 1). At the time of the site visit inspection, CAMSTRAC had recently run two pilot training courses. The courses were used to test procedures and received positive feedback from delegates.

The visual inspection comprised a review of the following areas in the facility: seminar room, where delegates receive introductory training; delegate changing facilities; preparation room, where kits are prepared; the administration offices where records are stored; storage areas where fresh-frozen tissue is stored and the surgical training laboratory where surgical training takes place. The inspection also comprised interviews with the DI and key establishment staff as well as a review of documents. The facility employs administrative staff who maintain the donor records and hospital theatre staff who are responsible for receiving fresh-frozen tissue as well as ensuring that surgical instrument kits used in the training courses are decontaminated and cleaned in the dirty sluice room on site. Instruments that are loaned to

the establishment are decontaminated and cleaned on site and are then sent to Addenbrooke's Hospital to be autoclaved. This is carried out separately to the surgical kits used in actual surgery on patients.

Theatre staff, technical staff and the DI are responsible for receiving imported fresh frozen tissue and assigning a unique identifier to each specimen. The unique identifier is a sequential number which is pre-printed in the CAMSTRAC parts register. The tissue is received with brief donor medical history paperwork and confirmation of the tests performed on the donor for transmissible diseases e.g. Hepatitis B. A tag with the unique identifier is added to the specimen as well as written onto the specimen bag with indelible ink. Non-conforming specimens are quarantined in one of the freezers in the store room until the DI has resolved any issues.

The store room accommodates five freezers and one fridge. The room is secure and alarmed. The temperatures of the freezers and fridges are monitored daily. There are plans to fit an alarm and an auto dialling system to the freezers and fridges. The establishment also plans to procure a mechanical hoist to reduce the manual handling of large specimens, which currently require the assistance of several staff members. The specimens are removed from storage in advance of the surgical training to ensure that they thaw out in time for the course.

A reverse audit trail was carried out on two specimens, by testing whether they could be traced from the electronic database and paper records to storage. One of the specimens had recently been used in the pilot course. The first specimen was a shoulder that had been stored at Addenbrooke's hospital under the post mortem licence and was then transferred to CAMSTRAC for future surgical training. The second specimen was a pelvis to toe tip which was received into CAMSTRAC and was then divided into three parts. All donor medical history and testing records were present. As CAMSTRAC does not receive copies of the consent forms, the consent records for these specimens were not reviewed as part of the audit trail. No discrepancies were found.

At the time of the inspection, no disposal had taken place. However the DI was able to demonstrate evidence of specimens awaiting disposal.

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
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	At the time of the inspection, CAMSTRAC did not have any health and safety risk assessments in place. The only risk assessment in place was relevant to transport of human tissue between the organisations.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	As set out in the HTA's code of practice on import and export, imported material should be procured, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. The DI and CLHc visited the organisation in the USA to ensure that consent is obtained appropriately for surgical training, anatomical examination and research. The agreement between CAMSTRAC and the organisation in the USA stipulates that 'first person consent' is sought, however it does not state the individual purposes for which consent is in place. As a matter of good practice, the DI is advised to review the content of the agreement to assure himself that specimens received are consented for the purposes stated above.
2.	GQ1	As CAMSTRAC has been licensed for a short while, the DI is advised to hold meetings with staff engaged in licensable activities and to ensure that staff are aware of who the nominated PDs are. The actions arising from the meetings should be noted and followed up.
3.	GQ2	Whilst there is an audit and review SOP in place, the DI is advised to devise an audit template to capture any audits that are carried out. The DI is advised to implement Corrective and Preventative Actions Plans (CAPAs) where issues are identified. There should also be provision to record when any completed CAPAs are then formally closed.
4.	GQ6	The Serious Adverse Events (SAE) SOP should be amended, as it currently reflects the definition of an SAE, and reporting timeframes, under the Quality and Safety Regulations for Human Application 2007. This should be removed as it may cause confusion. The DI should consider adding information of the types of incidents that should be reported internally. This could include storage failure, loss of records, loss of traceability, loss of specimen, non-confirming packaging/products. A CAPA (corrective and preventative action) plan system could be used to identify and monitor actions required
5.	GQ7/PFE4	CAMSTRAC has in place a risk assessment that covers transportation of specimens. The DI is advised to consider the use of data loggers, as currently specimens are transported on dry ice. Use of data loggers might help to assure the DI that specimens are maintained at the optimum temperature during transport.

		The DI is also advised to consider widening the scope of risk assessments to cover other relevant risks to human tissue. This may include loss of specimens, loss of traceability, and storage failure out of hours.
6.	PFE1	The DI is advised to document a risk assessment of the premises, taking into account the safety of delegates attending surgical training. Furthermore, as the specimens arrive through a communal seating area, the DI is advised to consider the risks of using this area for specimen receipt and transit. The DI should also consider appropriate signage in the facility to ensure that staff and delegates are aware of 'clean' and 'dirty' areas.
7.	PFE2/PFE5	The DI is advised to implement a cleaning and decontamination schedule for fridges and freezers storing fresh-frozen tissue, which can be used to record when these have been done. The DI is also advised to keep copies of all maintenance records at CAMSTRAC, to enable staff to monitor the maintenance of equipment.
8.	PFE3	At the time of the inspection, the temperature of the fridge and freezers were being monitored daily and the DI was in the process of purchasing an alarm system with an auto-dialling function. Once this has been installed, the DI should consider testing of fridge and freezers to challenge the functioning of the alarm.

Concluding comments

The DI and establishment staff demonstrated a cohesive working relationship, which is reflected by the conscientious approach adopted to develop the systems that support the activities in CAMSTRAC. The CAMSTRAC Director is responsible for developing the strategic aims of the facility, and discusses the progress and development of the facility at the Management Board which meets formally at Addenbrooke's Hospital. The DI is experienced in HTA compliance and has developed a sound quality manual and detailed standard operating procedures (SOPs). The DI also ensures that all delegates attending are provided with an induction focussing on the codes of conduct in the surgical training laboratory as well as ensuring that delegates have an understanding of the HTA Act 2004.

The traceability systems have been developed well, with the use of a parts register which is completed by staff receiving specimens. The parts register is then provided to the facility's administrator who has access to the database and is responsible for updating this regularly. Particular attention has been given to develop a system for splitting specimens and ensuring that traceability for each part is maintained.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 25 September 2013

Report returned from DI: 3 October 2013

Final report issued: 14 October 2013

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: 31 October 2013

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.