Inspection report on compliance with HTA licensing standards
Inspection dates: **2 October (remote) and 3 October (site visit) 2024**

Charles Wolfson Centre for Reconstructive Surgery
12709

Licensed under the Human Tissue Act 2004

Licensed activities

Area	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	Storage of an anatomical specimen
Charles Wolfson Centre for Reconstructive Surgery	Licensed	Not licensed	Licensed	Not licensed

Summary of inspection findings

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

Charles Wolfson Centre for Reconstructive Surgery ('the establishment') was found to have met all of the HTA's standards.

Advice

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

Number	Standard	Advice
1.	GQ1(b)	The establishment does not have an overarching document management system for standard operating procedures (SOPs) and risk assessments. Instead, the DI stores these documents on a local secure drive which is accessible to the DI only. The DI is advised to consider should how key documents can be made accessible to staff involved in licensable activities; for example, if the DI is unavailable.
2.	GQ3(b)	The establishment delivers up to eight courses throughout the year to qualified clinicians, surgical trainees, nurses, and post-graduate students for MSc programmes. The establishment does not deliver a set programme of courses and therefore does not have a full time technician to support these activities. Instead, the establishment has access to bank staff, with relevant expertise to support the DI to deliver each course. The technicians are inducted each time they attend and are required to complete an induction checklist for each course they provide support for. The checklist is intended to evidence that they have been appropriately trained prior to supporting the DI. To strengthen this further, the DI should consider expanding the checklist to include: the name of the course and date; the version numbers for each SOP reviewed by the technician; key tasks the technician must be competent in prior to supporting a course, and; a competency sign-off process by both the technician and the DI (or PD).

3.	GQ5(a)	The establishment's adverse event SOP provides detail on reporting incidents through the internal reporting system. It was noted during the inspection that the establishment had not reported an incident internally as it was unclear to the DI whether it needed to be reported. To provide clarity and reduce the risk of non-reporting, the establishment is advised to review and revise the SOP, making it clear that all incidents must be reported internally.
4.	PFE2(d)	The establishment stores frozen body parts that are imported from outside of the UK. There are appropriate documented contingency arrangements in place to deal with freezer failure. Specimens are stored overnight to be thawed out the following working day, in preparation for each course. In the event that a freezer failure should occur, as the specimens will be removed from the freezer in the morning, the establishment acknowledges any alarm notifications that occur out of hours, however, should a problem arise out-of-hours, staff will not attend until the morning as the establishment deems that there is limited risk to the material. The DI is advised to document this approach, making it clear how freezer failures are to be dealt with prior to a weekend or public holiday.

Background

The Charles Wolfson Centre for Reconstructive Surgery is a national centre for reconstructive surgery. The establishment imports material from deceased donors from outside of the UK under an agreement and will store material for a short period of time, prior to its use in surgical skills training. All material is disposed of after a course is complete.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

Of the 47 HTA standards, 39 were assessed (standards published 3 April 2017). Standards C1(a),(b),(d),(e) and (f) and C2(a),(b) and (c) were not applicable at the establishment is not involved in seeking consent.

Review of governance documentation

A number of documents were reviewed during the assessment which included, but were not limited to, standard operating procedures for licensable activities, key policies, traceability audits, meeting minutes, staff training records, temperature monitoring data and incident reports.

Visual inspection

A visual inspection of the premises where human material is stored and used was undertaken during the site visit component of the inspection.

Audits

Audits undertaken during the inspection focussed on records only, as there was no human material being stored at the time of the inspection. A review of records relating to human material imported for three different courses was carried out.

Course 1

The audit trail focussed on the review of traceability records, donor history, consent and disposal records relating to five specimens. The records were complete and there were no discrepancies identified.

Course 2

The audit trail focussed on the review of traceability records, donor history, consent and disposal records relating to five specimens. The records were complete and there were no discrepancies identified.

Course 3

The audit trail focussed on the review of traceability records, donor history, consent and disposal records relating to five specimens. The records were complete and there were no discrepancies identified.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff which included the DI, Charles Wolfson Centre Director, Person Designated (PD) and Head of Quality and Licensing.

Report sent to DI for factual accuracy: 28 October 2024

Report returned from DI: 8 November 2024 (with comments)

Final report issued: 18 November 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 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.

Its programme of 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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