

Licence application assessment report on compliance with HTA licensing standards  
Site visit date: no visit undertaken



## Charles Wolfson Centre for Reconstructive Surgery

Proposed HTA licensing number 12709

Application for a licence under the Human Tissue Act 2004

### Activities applied to be licensed

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	Applied to be licensed	Not applied to be licensed	Applied to be licensed	Not applied to be licensed

### Summary of findings

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

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

## Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

## Advice

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

Number	Standard	Advice
1.	GQ2(a)	The proposed DI is advised to conduct horizontal audits in addition to the planned vertical and external audits. Horizontal audits should be conducted by staff involved in the processes to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. The proposed DI may also wish to conduct audits against the relevant <a href="#">HTA standards</a> .
2.	GQ3(b)	The proposed DI is advised to review the documented induction training programme to ensure it explicitly includes training for staff in the requirements of the Human Tissue Act 2004 and the relevant HTA Codes of Practice.
3.	PFE2(b)	The proposed DI is advised to consider the agreements in place with the DI at the HTA-licensed mortuary to ensure that they detail the arrangements for the storage, monitoring and transfer of specimens to the training room.

## Background

The Charles Wolfson Centre (CWC) for Reconstructive Surgery (the establishment) is a new facility that is based at the Royal Free Hospital. The establishment proposes to host training and teaching courses for surgeons and healthcare professionals.

The establishment will purchase fresh-frozen specimens from the UK and overseas. There are Material Transfer Agreements in place with organisations, that cover: consent from donors, donor testing, courier transport to the establishment and full traceability.

The proposed DI is a Lecturer at the establishment. The proposed Corporate Licence Holder (CLH) is the Royal Free London NHS Foundation Trust and the proposed CLH contact is a Professor of Plastic and Reconstructive Surgery. The proposed Person Designated is a Portfolio Manager.

### **Description of activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk-based assessment.

#### *Standards assessed*

40 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Some standards relating to consent procedures (C1(a), C1(d), C1(e), and C1(f)) and standards relating to consent training (C2(a), C2(b) and C2(c)) were not applicable as the establishment does not directly seek consent from donors.

#### *Review of governance documentation*

Policies and procedural documents relating to all licensed activities, including standard operating procedures, risk assessments and traceability systems were assessed. Documents detailing the plans for staff training, adverse events, incidents, governance meetings and audits were also reviewed.

#### *Visual inspection*

There was no site visit inspection associated with the licence application; however, photographs and site plans of the facilities were provided.

#### *Meetings with establishment staff*

The assessment also included a meeting with the Chief Medical Officer, proposed Designated Individual (DI), proposed Corporate Licence Holder contact (CLHc), proposed Persons Designated (PD), Head of Quality and Licensing and technical staff working under the licence.

**Report sent to proposed DI for factual accuracy: 15 February 2021**

**Report returned from proposed DI: 25 February 2021**

**Final report issued: 01 March 2021**

## **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 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, and;
- 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, or;
- 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 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 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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

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