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

Cambridge Consultants Ltd

Proposed HTA licensing number 12705

Application for a licence under the Human Tissue Act 2004

Activity to be licensed

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Cambridge Consultants Ltd	To be licensed	Not to be licensed

Summary of assessment 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 found that Cambridge Consultants Ltd (the 'establishment') had met all of the HTA's standards.

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Proposed DI and proposed CLH suitability

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

Advice

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

Number	Standard	Advice
1.	N/A	The proposed DI is advised to consider appointing a Person Designated (PD) to assist her in the role. This would be especially important on those occasions when the DI is absent. The HTA must be notified of such an appointment.
2.	T1(c)	The proposed DI is advised to consider highlighting freezers and liquid nitrogen storage vessels ('cryovessels') that contain human tissue to prevent sample mix-ups, to ensure full traceability and to ensure that staff are aware of the need to manage such samples in line with the regulatory requirements.
3.	PFE2(c)	The establishment has a -20^{o}C freezer for receipt of human tissue, a cryovessel for long term storage and a -80^{o}C freezer as contingency storage. Although the temperatures of the freezers and cryovessel are monitored, there is no temperature monitoring at weekends or during vacation periods. The proposed DI is advised to consider risk assessing the current arrangements for monitoring and recording temperatures and the effects that storage temperature deviations could have on the quality of samples stored.

		In light of this advice, the proposed DI is further advised to consider: • regular challenging of the freezer and cryovessel audible temperature alarms to ensure that they function as expected. • initiating a programme by which, at suitable intervals, the temperature plots from the freezers are reviewed. This may help to identify a potential failure of this equipment before it occurs.

Background

Cambridge Consultants Ltd ('the establishment') has applied for an HTA licence to store relevant material purchased from commercial suppliers, or material supplied by clients, to aid the development of new medical devices.

Description of activities undertaken during the assessment

There was no site visit. During the assessment, the Regulation Manager covered the following areas:

Standards assessed against

There are 47 standards under the Human Tissue Act 2004 ('HT Act'). Several standards could not be assessed as the establishment will not directly seek consent [standards C1(a)-(b), C1(d)-(f) and C2(a)-(c)], have visiting staff [GQ3(c)] or store material from the deceased [PFE2(b)]. All other standards were assessed (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed; temperature monitoring records; contracts for servicing of equipment and records of servicing; template agreements.

The review of information related to the quality management system included staff training records and risk assessments.

Meetings with establishment staff

A telephone conference call was held with the proposed DI and proposed CLH contact. This covered: document control; the management of audits; incidents and risk assessments; temperature monitoring of storage facilities; contingency and disposal arrangements.

Report sent to proposed DI for factual accuracy: 10 November 2020

Report returned from proposed DI: 16 November 2020

Final report issued: 27 November 2020

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
- 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 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
- 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.