Licence application assessment report on compliance with HTA licensing standards
Assessment date: **22 June 2021**

Charles River Discovery Research Services
Proposed HTA licensing number 12708

Application for a licence under the Human Tissue Act 2004

Activities applied 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
Charles River Discovery Research Services UK Ltd (Hub)	Applied to be licensed	Not applied to be licensed
Charles River Discovery Research Services (Satellite)	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.

Although the HTA found that Charles River Discovery Research Services (the ‘establishment’) had met the majority of the HTA’s licensing standards, three minor shortfalls were found in relation to consent procedures, standard operating procedures (SOPs) and risk assessments.

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.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes 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	Although staff at the establishment do not seek consent directly, procedures relating to the assurance that consent is in place, and how to deal with issues such as consent withdrawal, are not documented.	**Minor**
GQ2 There is a documented system of audit		
(a) There is a documented schedule of audits	The audit schedule does not include any audit activities that would provide assurances about the effectiveness of sample traceability.	**Minor**
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	There is an SOP that sets out how staff should document risks; however, there are no risk assessments for practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	To strengthen the identification and management of procedural documents, the proposed DI is advised to consider renaming the SOP 1.11 (titled, 'Labelling, tracking and storage of human tissue'), as it also covers consent arrangements and disposal processes.
2.	GQ1(a)	Consent requirements and exemptions are detailed within SOP1.11. Currently, it is stated that *'consent is not required when material is imported'*. The proposed DI is advised to reword section 3.1 to reflect the expectations for imported material set out in the HTA's Code of Practice on Research.
3.	PFE2(c)	An email notification is sent when temperature-controlled storage areas deviate from set temperature ranges. The proposed DI is advised to include the email addresses that are on the notification list in the relevant document/s. This is to ensure that up-to-date contact details are clear to staff.
4.	PFE2(d)	Contingency arrangements are documented; however, the current SOP does not detail the exact locations of the contingency fridges and freezers.The proposed DI is advised to detail this to ensure that staff are aware of the full range of actions to be taken in the event of an alarm.

Background

Charles River Discovery Research Services is a contract research organisation that performs research studies in the areas of cell biology, immunology, infection and pharmacology. The establishment has applied for a HTA licence for the storage of relevant material, which has come from a human body, for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.

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

Review of governance documentation
Policies and procedural documents relating to all licensable activities - including policies, standard operating procedures and traceability systems - were assessed. Documents detailing the plans for staff training, incident management, governance meetings and audits were also reviewed.

Visual inspection
There was no site visit.

Meetings with establishment staff
The assessment also included a virtual meeting with the proposed Designated Individual (DI).

Report sent to proposed DI for factual accuracy: 14 July 2021

Report returned from proposed DI: 19 July 2021

Final report issued: 19 July 2021

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 Licence Application Assessment Report.

Date: 26 07 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.