Licence application assessment report on compliance with HTA licensing standards
Assessment date: **17 August 2023 (site visit)**

MSD London

Proposed HTA licensing number 12757

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
MSD London	Applied to be licensed	N/A
The Francis Crick Institute	Applied to be licensed	N/A

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.

MSD London (‘the establishment’) was found to have met most of the HTA standards; however, two minor shortfalls were identified against standards for Governance and quality systems, specifically in relation to procedures and risk assessments linked to HTA-licensed activities.

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

Compliance with HTA standards

Minor shortfalls

Standard	Assessment Findings	Shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	The establishment plans to store tissue from deceased donors for use in research. The standard operating procedure (SOP), ‘working with human tissue, SOP 8’ does not set out the steps that staff are expected to take to ensure that the applicable consent requirements have been met. *“The establishment submitted sufficient evidence to address this shortfall before the report was finalised.”*	**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.	The establishment had undertaken only a biological human tissue risk assessment. There was no assessment of risks associated with activities, such as storing material without assurance of consent, sample mix-up, loss of traceability and incorrect disposal. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	'HTA SOP 8' covers the process for logging samples on the traceability system. Section 6 of the SOP states that staff must log samples 'ideally on the day of receipt or within 7 days'. The proposed DI should consider adding a rationale for this length of time and also consider whether there are any risks posed to sample traceability where samples are not logged immediately.

2.	PFE1(a)	The establishment had undertaken a risk assessment focussing on the suitability of the premises and security. The proposed DI is advised to consider strengthening the assessment using a risk matrix scoring approach, allowing risks to be ranked and managed accordingly.
3.	PFE2(c)	The freezer that will contain human tissue at the hub site is subject to continuous temperature monitoring. The proposed DI should consider adding the freezer and fridge at the satellite site onto a temperature monitoring system, should they contain human tissue in the future. This would provide assurances that critical storage conditions at the satellite site were monitored in a way consistent with the hub site arrangements.
4.	PFE2(d)	The proposed DI should consider adding a copy of the onsite contingency locations in the areas where human tissue is stored. This will help ensure staff are aware of where to transfer tissue in the event of a freezer breakdown.

Background

The prospective establishment is a pharmaceutical company that aims to research, develop and supply new medicines and vaccines that prevent and treat diseases that occur at every stage of life, with a particular focus on diseases of ageing and neurodegeneration. The establishment plans to store human tissue from the living and deceased which will be supplied from third parties and HTA-licensed research tissue banks. The establishment will not be involved in consent-seeking activities and will store tissue that has associated donor consent for storage for use in research.

Description of activities undertaken during visit

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

Standards assessed against during visit

Of the 47 standards, 41 standards were assessed (standards published 3 April 2017). Standards, C1(d)(e) and (f), C2(a)(b) and (c) were not applicable because the establishment will not be seeking consent.

Review of governance documentation

Key SOPs and policies were reviewed as part of the licence application assessment which covered licensable activities such as receipt, storage, transport and disposal of human tissue.

Visual inspection

A tour of the storage areas at the hub and satellite site were undertaken at the time of the licence application assessment. The facility was accessible by swipe card access only and had appropriate temperature monitoring in place at the hub site.

Meetings with establishment staff

A roundtable discussion was carried out with the proposed Designated Individual (DI), proposed Corporate Licence Holder contact (CLHc) and three members of staff taking on the roles of Persons Designated (PDs) at the hub and satellite sites.

Report sent to proposed DI for factual accuracy: 7 September 2023

Report returned from proposed DI: 9 October (no comments)

Final report issued: 19 October 2023

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.