Licence application assessment report on compliance with HTA licensing standards
Assessment date: **1 November 2022**

TTP Plc

Proposed HTA licensing number #12734

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
TTP Plc	Applied to be licensed	Not applied to be licensed

Summary of visit 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 TTP Plc (the 'establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems, and Premises, facilities and equipment. The shortfalls identified were related to consent training, Standard Operating Procedures and risk assessments for licensable activities, and monitoring of storage units for relevant material.

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 visit.

Compliance with HTA standards

Minor Shortfalls

Standard	Visit findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	There was no structured, formalised training for staff involved in seeking consent which addresses the requirements of the HT Act and the HTA's Codes of Practice.	**Minor**

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 did not have documented policies and procedures related to all licensable activities. From the documents reviewed, there were no Standard Operating Procedures (SOPs) that covered: • receipt of samples • monitoring of storage conditions • adverse event management	**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 are no documented risk assessments relating to the premises, practices and procedures connected with licensable activities.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	The temperature monitoring records for the fridge and -20°C freezer were reviewed. Temperature excursions outside tolerances specified in the Human Tissue Handling standard operating procedure were identified, but no action/s had been taken due to a lack of clarity about the procedure staff should have followed.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The proposed DI is advised to implement procedures to ensure they have appropriate oversight of activities occurring, and relevant material being stored, under the licence. Currently individual project group leaders are responsible for ordering relevant material with no requirement for notification or approval from the proposed DI.

2.	GQ2(a)	To provide improved and consistent oversight, support and follow-up, the proposed DI is advised to consider whether it would be beneficial to incorporate HTA-related audits into the establishment's wider governance framework. Planned audits should cover all HTA licensable activities and include both horizontal and vertical process audits to provide an assurance that processes are being followed correctly and that the documented procedures continue to reflect current practice.
3.	T1(c)	The proposed DI is advised to label all refrigerators and freezers that are intended to contain human tissue so that staff are aware of the necessity to maintain the quality, safety and security of the stored material.
4.	PFE1(b)	The proposed DI is advised to implement a procedure for locking the -80°C freezer to prevent unauthorised access to relevant material.
5.	PFE2(c)	The proposed DI is advised to consider recording the minimum and maximum temperatures reached by fridges and freezers when manually recording the daily temperatures. This will provide an assurance that there have been no deviations from the defined temperature ranges between readings. In addition, it is advised that back-up fridges and freezers are temperature monitored to ensure that they are functioning within expected ranges should they be needed for contingency storage.
6.	PFE3(a)	The proposed DI is advised to consider moving the storage units and temperature monitors onto a preventative maintenance service contract when the current manufacturers' warranty expires.

Background

TTP Plc has applied for an HTA licence to store relevant material which has come from a human body for use for a scheduled purpose; namely, research in connection with disorders, or the functioning, of the human body. TTP Plc is a product development consultancy that undertakes contract research and development across a broad spectrum of fields including Life Sciences and Health Technology. Relevant material to be held under the licence will either be stored at -80°C, -20°C or under refrigerated conditions.

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 visit:

Standards assessed against during visit
There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not intend to store material from the deceased (standards published 3 April 2017).

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, risk assessments, arrangements for temperature monitoring for the refrigerated and ambient storage units, and a review of the HTA Sample Database that will be used to record and track relevant material.

Visual inspection
The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment and stored.

Meetings with establishment staff
The assessment included meetings and discussions with the proposed DI, the proposed Corporate Licence Holder contact, a representative of the building facilities team, and the Quality Assurance Manager.

Report sent to proposed DI for factual accuracy: 28 November 2022

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 6 December 2022

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 Inspection Report.

Date: 27 January 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.