Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **30 March (remote) and 13 April (site visit) 2022**

Pathfinder Medical

Proposed HTA licensing number 12732

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
Pathfinder Medical	Applied to be licensed	N/A

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.

Pathfinder Medical ('the establishment') was found to have met all the HTA standards.

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

Compliance with HTA standards

All applicable 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)	Although the establishment has in place a comprehensive audit procedure (*QP1 Internal Auditing Procedure*), the prospective DI may wish to consider adding detail on the scope of the HTA audits; for example, the areas that will be covered as part of the audit process. This may help to strengthen the establishment's demonstration of compliance with our standards and whether they are meeting the requirements of their own systems.
2.	GQ5(a)	To further support staff awareness and understanding in adverse incident reporting, the prospective DI is advised to consider including examples of incidents involving human tissue in the procedure, *QP3, Corrective Action NCR Form*. These could reflect the risk areas identified in the risk assessment.
3.	PFE2(c)	The -20°C freezers which will store the body parts will remain switched off unless human material is stored within the freezers. The prospective DI is advised to test the alarm systems before material is stored to ensure that they are working as expected, particularly if they are off for long periods of time.
4.	PFE2(c)	To strengthen staff awareness, the prospective DI is advised to consider placing information on the doors of freezers to reinforce the expected storage temperature ranges.

5.	T2(a)	Although there are no plans for the establishment to dispose of the body parts, this may change moving forward. In the event that disposal is carried out, the relevant procedure, *F073 Purchase and Disposal of Human Tissue*, should be updated to reflect the steps to be undertaken if disposal is managed internally. Furthermore, the DI may wish to take into account the disposal wishes of the donor or family of the imported material, in case there are any specific requirements.

Background

Pathfinder Medical (the establishment) is a Medical Device Company that plans to work with fresh frozen body parts (deceased donors) which will be purchased and imported from outside of the UK for use and storage in research. The body parts will be stored for clinical research studies.

Only staff who have appropriate experience and training will be involved in handling the body parts and there are no plans to run any external training using this material.

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

Thirty-nine of the 47 HTA licensing standards were covered during the visit (standards published 3 April 2017). C1(a)(b)(d)(e) and (f) and C2(a) - (c) were not applicable as the establishment staff will not be directly seeking consent.

Review of governance documentation

Key documents (i.e. Standard Operating Procedures (SOPs)) were reviewed during the virtual assessment, including but not limited to, the following:

- Handling and Storage of Human Tissue (SOP);
- Purchase and Disposal of Human Tissue (SOP);
- Quality Manual (SOP);
- Internal Auditing Procedure (SOP);
- Traceability system (Excel);
- Assessment of risk to Human Tissue ;
- Human Tissue Risk Report;
- Training (SOP)

Visual inspection

A site visit was undertaken as part of the assessment. The areas where licensable activities would be undertaken were visually inspected, including the area where the body parts would be received, checked and subsequently stored.

Meetings with establishment staff

A roundtable discussion was carried out with the proposed DI and CLHc.

Report sent to proposed DI for factual accuracy: 27 April 2022

Report returned from proposed DI: 27 April 2022 (with comments)

Final report issued: 28 April 2022

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.