Licence application assessment report on compliance with HTA licensing standards
Assessment date: **24 February 2022**

Perspectum

Proposed HTA licensing number 12727

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
Hub site **Perspectum**	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.

Perspectum (the establishment) was found to have met all HTA standards.

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

Compliance with HTA standards

All applicable HTA 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.	PFE2(c)	In line with HTA guidance, the proposed DI is advised to implement the following: • regular checks of temperature monitoring records for critical storage units, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure, and; • periodic tests of the temperature alarms of critical storage units, which may include manual challenges of alarms and the call-out system to ensure they are operating as expected.
2.	N/A	The proposed DI is advised to identify 'Person(s) Designated' to assist them in ensuring compliance with HTA standards.

Background

The Clinical Facility at Perspectum Oxford headquarters houses the newly built Gemini Laboratory. The Clinical Facility currently carries out ethically approved clinical research activities and provides a Community Diagnostic Centre, in collaboration with the NHS.

Perspectum staff perform research for clinical research trials that have approvals from recognised Research Ethics Committees (RECs) for Perspectum-sponsored and externally-sponsored Clinical Investigations. Staff consent participants, perform study procedures and collect human biological samples, usually blood. The processing of blood samples - or their derivatives - for analysis, and short-term storage activities of the samples under study-specific recognised REC approval, will be performed in-house. The Gemini Laboratory will also receive blood and/or tissue samples from other trial sites for processing and storage centrally. These samples are currently processed and stored for the duration of the Clinical

Investigation only under the study-specific recognised REC approval.

Proposed activities under the licence will include consent and storage of samples for further research once the clinical trial has concluded.

Description of activities undertaken during assessment

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 assessment

There are 47 standards in the Research sector, 45 of which were assessed. Standards T1(g) and PFE2(b) were not applicable as the establishment does not intend to distribute relevant material for the foreseeable future, or store material from the deceased (standards published 3 April 2017).

Review of governance documentation

Policies and procedural documents relating to all licensable activities, including the establishment's Quality Manual, standard operating procedures, risk assessments and those pertaining to traceability system were reviewed. Documents detailing monitoring, adverse events, incident management and governance meetings were also reviewed.

Visual inspection

No site visit was undertaken as part of the licence application assessment. However, the Regulation Manager reviewed laboratory site plans where relevant material will be stored, temperature monitoring systems for critical storage units and security arrangements for the premises.

Meetings with establishment staff

The assessment included remote meetings with the proposed DI, the proposed Corporate Licence Holder contact, Clinical Affairs Specialist and Clinical Trials Manager.

Report sent to proposed DI for factual accuracy: 21 March 2022

Report returned from proposed DI: 4 April 2022

Final report issued: 7 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.