Licence application assessment report on compliance with HTA licensing standards
Site visit date: **23 March 2023**

PhoreMost, Unity Campus

Proposed HTA licensing number 12755

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
PhoreMost **The Works, Unity Campus, Pampisford, Cambridge**	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 PhoreMost, Unity Campus (the ‘establishment’) had met the majority of the HTA’s standards, two minor shortfalls were found against standards for Consent and Governance and quality systems.

The HTA has assessed the establishment as suitable to be licensed for the activities specified. No CAPA plan will be issued as the establishment submitted sufficient evidence to address the shortfalls before the report was finalised.

Compliance with HTA standards

Minor Shortfalls

Standard	**Visit findings**	**Level of 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 did not have a standard operating procedure (SOP) covering the monitoring of storage conditions and the actions to be taken in the event of a temperature excursion. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

c) There are change control mechanisms for the implementation of new operational procedures.	The establishment had no change control mechanisms for the implementation of new operational procedures, taking into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed. *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)	The proposed DI is advised to reference the annual audit of Advent Bioservices in SOP HSP-004 Human Tissue Act Policy to ensure all audit activities are identified and documented.
2.	GQ1(a)	The proposed DI is advised to include the process step of sending relevant material delivery receipts to the Purchase Team in HTA-SOP-002 Sample Purchasing, Tracking and Documentation to ensure the written procedure reflects actual practice. In addition the proposed DI is advised to consider including a sample receipt checklist within HTA-SOP-002 to be used by staff when taking receipt of relevant material to ensure consistency and to identify inaccuracies.
3.	GQ1(d)	Governance meetings are to be held every 6 months to discuss HTA licensed activities. The proposed DI is advised to consider producing a standing agenda with relevant headings in HTA-FORM-001 to ensure all areas

		relating to the licence are identified and discussed during governance meetings.
4.	GQ5(a)	HTA SOP-001 Adverse Event Reporting requires serious adverse events or reactions to be reported through the online HTA portal, which reflects obligations for those working under Human Application sector licences. The proposed DI is advised to amend this wording as there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA. If the proposed DI has concerns about an adverse event, they are encouraged to contact the HTA for further advice.
5.	T2(b)	The tissue tracking database has free text boxes to record the reasons and methods of disposal. The proposed DI is advised to consider creating a drop down menu within the tissue tracking database listing the reasons for disposal and the disposal methods for relevant material that align with options available in HSP-005 Waste Disposal Policy. This would help to ensure that procedures reflect practices and increase the accuracy with which the database can be searched.
6.	PFE1(c)	There are documented cleaning and decontamination procedures and the proposed DI is advised to keep a record to provide evidence that cleaning has taken place. Further, the proposed DI is advised to include the frequency that fridges and freezers are to be cleaned and decontaminated within HSSOP-002 Cleaning and decontamination in containment level 1 & 2 laboratories.
7.	PFE3(b)	Equipment problems can be reported via the establishment's online intranet form. The proposed DI is advised to signpost new starters to this form during the induction process to ensure equipment users are aware of how to report problems.

Background

PhoreMost is biotechnology company focusing on drug research to increase the diversity of novel therapeutics for cancers and other diseases.

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

43 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Four standards were not applicable as the establishment does not have staff involved in seeking consent [standards C2(a), (b) and (c)] and does not intend to store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

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, adverse event reporting, training requirements, temperature monitoring for the refrigerated units, equipment servicing records and a review of the HTA tissue tracking 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 and the proposed Corporate Licence Holder contact.

Report sent to proposed DI for factual accuracy: 21 April 2023

Report returned from proposed DI: 28 April 2023

Final report issued: 2 May 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.