Inspection report on compliance with HTA licensing standards
Inspection date: **11 October 2022**

Gravelly Park

HTA licensing number 12347

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Gravelly Park**	Not Licensed	Not licensed	Licensed
Storage Unit	-	-	-

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Gravelly Park ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against the standards for Premises, facilities and equipment. This related to testing of the freezer alarms.

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 inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Whilst the freezer units are monitored regularly, are alarmed and alarms work as expected, the alarm system is not tested.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	PFE1(c)	Whilst the storage units were clean at the time of the inspection and it is evident routine cleaning is conducted from discussion with establishment staff, the DI is advised to ensure the monthly cleaning is recorded consistently.

2.	PFE1(d)	The DI is advised to ensure that external freezer unit components are rehoused in the provided casing and made secure following maintenance.

Background

Gravelly Park has been licensed by the HTA since February 2008. This was the third inspection of the establishment; the most recent previous inspection took place in July 2018.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. At the time of the inspection the establishment were not storing any relevant material under the HT Act as all material held fell under the Section 39 exemption of the HT Act (material held under PACE). The establishment continue being licensed by the HTA in the event material falls outside of the exemption whilst awaiting collection from storage. In this event, systems are in place to identify material held under the HT Act.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

The following standards were not covered during inspection: C1 and C2 standards (11 in total), GQ1(b), GQ3(g), T1(d), T1(e), T1(f), T2(b), T2(c), T2(d), PFE1(b), PFE2(c), PFE2(g), PFE2(h), PFE3(b), PFE3(c) and PFE3(e). This means out of the total 72 standards 26 were not covered as these standards were not applicable. The establishment are a storage only facility and do not seek consent, conduct consented PM examinations, have visiting staff working at the facility, store bodies of the deceased or conduct disposal of material as material is returned to the establishment of origin for disposal.

Review of governance documentation
The inspection team reviewed policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, traceability documentation and staff training records.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the storage area of material held.

Audit of records
Audits were conducted of material held for six cases. Information was crosschecked between the establishments traceability database, which included the location and type of material being stored and the material in storage. Two cases reviewed demonstrated material had been returned to the establishment requesting storage. The further four cases demonstrated they were being held in line with the section 39 exemption. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with a member of staff carrying out processes under the licence who is also the quality manager and a Persons Designated and the DI.

Report sent to DI for factual accuracy: 21 October 2022

Report returned from DI: 31 October 2022

Final report issued: 31 October 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: 19 December 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 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
- 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
   - 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 inspection.

   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 both the draft and 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.