Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **13 February 2020**

Northwick Park Institute for Medical Research [The Griffin Institute]

Proposed HTA licensing number 12700

Application for a licence under the Human Tissue Act 2004

Activities to be licensed

Area	Carrying out of an anatomical 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 a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
Northwick Park Institute for Medical Research [The Griffin Institute]	Not to be licensed	Not to be licensed	To be licensed	Not 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 Northwick Park Institute for Medical Research [The Griffin Institute] (the 'establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and Quality systems, and Premises, Facilities and Equipment.

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 site visit.

Compliance with HTA standards

Minor Shortfalls

Standard	**Visit findings**	**Level of shortfall**
GQ2 There is a documented system of audit.		
a) There is a documented schedule of audits covering licensable activities.	There is no documented audit schedule covering licensable activities. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard GQ2(a) is met.*	**Minor**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	The proposed audit plans do not cover compliance with the HTA's standards or demonstrate the establishment meets the requirements of their own systems. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard GQ2(b) is met.*	**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.	The risk assesments for licensable activities do not contain sufficient detail of mitigating factors. In addition, there is no risk assessment for lone-working. *The establishment submitted evidence prior to the publication of this report to demonstrate that standard GQ6(a) is met.*	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The 'Return or Disposal Policy' currently states that relevant material will be disposed of via incineration at the establishment. During discussion with the establishment staff, it was stated that arrangements were being made for relevant material to be disposed of via a local Funeral Director. The proposed DI is therefore advised to update the 'Return or Disposal Policy' to reflect any new arrangements for disposal.
2.	T1(c)	The proposed DI is advised to label appropriately the refrigerators and freezers that contain human tissue. This will raise awareness of such material, helping to maintain its quality, safety and security, and helping to prevent mix-ups with other tissues.
3.	PFE2(c)	The proposed DI is advised to regularly test and manually challenge the temperature alarms for the refrigerators and freezers. These checks will provide assurances that the call-out procedures are working and that the alarms are operating as expected. Relevant SOPs should be updated to reflect these checks.

Background

The establishment has applied to be licensed under the Human Tissue Act 2004 (HT Act) for the storage of the body of a deceased person, or

relevant material which has come from a human body, for use for a scheduled purpose. In this case, material from deceased donors will be stored for education and training relating to human health. The establishment will purchase fresh-frozen specimens from the UK and overseas. There are Material Transfer Agreements in place with organisations that cover consent from donors, donor testing, courier transport to the establishment and full traceability.

The proposed DI is the Director of Training at the establishment and specialises in colorectal surgery. The proposed Corporate Licence Holder (CLH) is the Northwick Park Institute of Medical Research and the proposed CLH contact is the Chief Executive Officer for The Griffin Institute. One Person Designated (PD) will also be notified to the HTA.

Description of activities undertaken

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

Out of the total of 47, standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c) could not be assessed as the establishment will not directly seek consent (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed policies and procedural documents relating to licensable activities, cleaning SOPs for the storage areas and training rooms, proposed audits, risk assessments, incident recording, and staff induction and training plans.

Visual inspection

The inspection team visited areas from point of receipt of specimens, storage, preparation areas and training facilities.

Meetings with establishment staff

The inspection team met with the proposed DI, proposed CLH contact, proposed PD and establishment staff that will be carrying out processes under the licence.

Report sent to proposed DI for factual accuracy: 26 February 2020

Report returned from proposed DI: 2 March 2020

Final report issued: 6 March 2020

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
- 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 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
- 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.