Inspection report on compliance with HTA licensing standards
Inspection date: **19 October 2023**

NHSBT Liverpool

HTA licensing number 12608

Licensed under the Human Tissue Act 2004

Licensed activities

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 **NHSBT Liverpool**	Licensed	Licensed
Satellite site **Pulleyn Transport Limited**	Licensed	Not Licensed

At the time of the inspection, the following satellite sites were also licensed for ‘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’. These sites are supporting transplantation research:

1. University Hospitals Birmingham NHS Foundation Trust
2. Good Hope Hospital
3. Heartlands Hospital
4. Brighton and Sussex University Hospitals NHS Trust
5. North Bristol NHS Trust
6. University Hospitals Bristol NHS Foundation Trust
7. Belfast Health and Social Care Trust - Royal Victoria Hospital
8. Cambridge University Hospitals NHS Foundation Trust
9. Cardiff and Vale University Health Board
10. Cwm Taf Morgannwg University Health Board
11. University Hospitals Coventry and Warwickshire NHS Trust
12. Barts Health NHS Trust
13. Hull University Teaching Hospitals NHS Trust
14. The Walton Centre NHS Foundation Trust
15. University Hospitals of Leicester NHS Trust
16. University Hospitals of Leicester NHS Trust (separate premises to above)
17. Leeds Teaching Hospitals NHS Trust
18. Leeds Teaching Hospitals NHS Trust (separate premises to above)
19. Manchester University NHS Foundation Trust
20. Salford Royal
21. Newcastle upon Tyne Hospitals NHS Foundation Trust
22. Newcastle upon Tyne Hospitals NHS Foundation Trust (separate premises to above)
23. Nottingham University Hospitals NHS Trust

24. University College London Hospitals NHS Foundation Trust
25. Royal Free Hospital
26. Oxford University Hospitals NHS Trust
27. University Hospitals Plymouth NHS Trust
28. Lancashire Teaching Hospitals NHS Foundation Trust
29. Brighton and Sussex University Hospitals NHS Trust
30. Barking, Havering and Redbridge University Hospitals NHS Trust
31. Sheffield Teaching Hospitals NHS Foundation Trust
32. Northern General Hospital
33. Swansea Bay University Health Board
34. King's College Hospital NHS Foundation Trust
35. University Hospital Southampton NHS Foundation Trust
36. University Hospitals of North Midlands NHS Trust
37. St George's University Hospitals NHS Foundation Trust
38. South Tees Hospitals NHS Foundation Trust
39. Imperial College Healthcare NHS Trust
40. Imperial College Healthcare NHS Trust (separate premises to above)
41. University College London Hospitals NHS Foundation Trust

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.

NHSBT Liverpool (‘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 DI to consider the following to further improve practices:

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to review establishment documentation and agreements to ensure that references to legislation are up-to-date, correct and appropriate. This will avoid confusion that may result in individuals being non-compliant with relevant legislation. For example: • the SOP related to The Retrieval, Logging, Storage, Supply Dispatch and Disposal of Tissues for Non-Clinical Use indicates that (in addition to the Human Tissue Act 2004 [HT Act]) the HTA regulates establishments under the 'EU Tissue and Cells Directive (2004/23/EC)', which is not the applicable domestic legislation. It also indicates that, under the HT Act, storage of cellular material must occur on licensed premises if it exceeds 48 hrs, which is not correct but is a requirement under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). • the agreement with the HTA-licensed organisation responsible for storing QUOD samples states '*that all Products are stored in appropriate conditions and segregated where required in accordance with the HTA Directions 001/2021*'. Samples stored under the HT Act for the scheduled purpose relating to research must comply with the legislative and regulatory frameworks for human tissue research rather than Directions 001/2021, which require compliance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

2.	GQ1(c)	The Specialist Nurse documents collection of QUOD blood and urine samples in a QUOD worksheet which is then provided to the National Organ Retrieval Service (NORS) team who complete a section detailing the tissue samples collected during organ retrieval. The completed form is sent with the samples to the HTA-licensed establishment responsible for storing the samples. The decision was made to no longer hold completed copies of the QUOD worksheet, due to delays in receiving copies of the completed forms. As the information is available on other ODT forms associated with the organ retrieval, and the completed forms could be requested if needed, the traceability risks associated with this decision are low. However, the DI is advised to document the rationale and any potential risks associated with this decision.
3.	GQ2(a)	The establishment undertook an audit of Research sector licensable activities in November 2021 as part of a site audit including Human Application (HA) sector activities. While the audit appeared to cover the relevant activities, the DI is advised to ensure that future audits are clear about which standards have been assessed in relation to the activities being audited.
4.	GQ2(a)	The DI is advised to document and expand the scope of vertical audits currently undertaken at the establishment to ensure they cover all licensable activities, and to consider implementing a schedule of procedural horizontal audits to ensure that SOPs accurately reflect the practices being carried out.
5.	GQ2(b)	The DI is advised to ensure that evidence of compliance detailing what was assessed during an audit is included within the audit report. This will allow a critical assessment of the audit findings when reviewing reports.
6.	PFE2(c)	The DI is advised to consider implementing a process to periodically challenge storage unit temperature alarms to provide an assurance that they are operating as expected.

Background

NHSBT Liverpool is part of National Health Service Blood and Transplant (NHSBT). NHSBT co-ordinates donations, obtains consent for donations, and retrieves, processes, tests, stores and distributes a diverse range of human tissue and cell products - including bone, skin, blood vessels and tendons - for use in surgery within hospitals and treatment centres in the UK. Relevant material that is not suitable for clinical use is stored within the NHSBT Liverpool Research Tissue Bank (RTB) and made available, with appropriate consent, for research and other scheduled purposes such as quality assurance. Relevant material is used within the NHSBT network, or may be provided to other researchers who have their own recognised Research Ethics Approval (rREC) and apply for material from the RTB.

In 2013, NHSBT launched the Quality in Organ Donation (QUOD) programme in collaboration with the Nuffield Department of Surgical Sciences at the University of Oxford, and a national consortium of transplant centres. Under the QUOD programme samples are collected, with consent, from deceased donors around the time of organ donation. Blood, urine and tissue samples are collected from donors at the hub or one of 41 satellite sites (see list earlier in this report), and stored in an RTB at another HTA-licensed establishment. More recently NHSBT has implemented the INOAR programme. INOAR stands for *Increasing the Number of Organs Available for Research* and makes untransplantable hearts, lungs and diabetic pancreases available for research studies that have their own project-specific rREC approval. Samples and tissues are collected, with appropriate consent, from deceased donors at one of the 41 satellite sites.

NHSBT Liverpool has been licensed under the Research sector licence number 12608 by the HTA since 2013. This was the first inspection of NHSBT Liverpool under licence number 12608, however, the establishment was previously licensed under the Post-mortem sector licence 12499. The most recent previous inspection of the 12499 licence took place in June 2010.

Since the previous inspection of the 12499 licence, a new DI, new Corporate Licence Holder contact, and several Persons Designated (PDs) have been appointed. In addition the establishment has rolled out the QUOD and INOAR programmes and added 42 satellite establishments to the licence.

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
All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, including consent procedures and template consent forms, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking spreadsheets and databases used to record and track relevant material, meeting minutes, agreements, audits, and incidents. Risk assessments of the 41 satellite facilities used to collect relevant material from the deceased as part of the QUOD and INOAR programmes are undertaken by the NORS team when retrieving organs at the time of collection. This is assessed during regular ODT audits and the risk assessments were not reviewed as part of this inspection.

Visual inspection
No site visit was undertaken as part of this inspection. However, the establishment provided a video tour and photographs of the storage facilities at the hub site that allowed an assessment of security around the storage units and the signage on the individual units. Removal of relevant material from the body of a deceased person under the QUOD and INOAR programmes at the hub and satellite facilities is undertaken by specialist nurses and a NORS team. While the process was discussed during the inspection, the sutability of the site is routinely assessed as part of audits under the HTA Organ Donation and Transplantation sector and was not visually assessed during this inspection. The establishment's Pulleyn Transport Limited satellite facility is used for the temporary storage of plasma prior to release to a commercial customer to be used for a scheduled purpose. Plasma is stored in a designated, secure, temperature-controlled and monitored area. While the facility was not visually assessed, the agreement defining the scope of activities and the most recent audit of the facility were reviewed.

Audit of records
Consent documentation and traceability records were reviewed for three donors under the QUOD programme, two donors under the INOAR programme, and a research sample released from the hub RTB. This included a review of applications for relevant material

including confirmation of rREC approval. In addition, a review of the most recent QUOD Donor file audit, the most recent audit of the Pulleyn Transport Limited satellite facility, the most recent internal audit report, and a review of the sample database and tissue discard database was undertaken.

Meetings with establishment staff
The inspection included discussions with the DI, PDs, and other staff working under the licence. This included local and national Quality Assurance representatives, the Quality Lead Specialist for the hub facility, The Head of Operations for Tissue and Eye Services, clinicians working under the licence, the NHSBT Liverpool RTB manager, ODT Specialist nurses involved with taking consent and samples in the QUOD and INOAR programmes, and staff involved with providing training.

Report sent to DI for factual accuracy: 13 November 2023

Report returned from DI: 27 November 2023

Final report issued: 6 December 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 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 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 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.