Inspection report on compliance with HTA licensing standards
Inspection date: **19 January 2022**

Northumbria University

HTA licensing number 12495

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 **Northumbria University**	Licensed	Not licensed

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 Northumbria University (‘the establishment’) had met the majority of the HTA’s standards, two minor shortfalls were found against standards for Governance and quality systems (risk assessments) and Traceability (disposal documentation).

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
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 establishment's risk assessments do not cover all potential risks relating to the premises, practices and procedures connected with licensed activities. For example, the current risk assessments do not adequately address risks associated with: • security arrangements; • the decision not to enter into preventative maintenance contracts for the freezer units; • the procedure for transferring samples to shared contingency storage in the event of a power failure; and • access arrangements during an incident (such as during the national response to the COVID-19 pandemic). ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**

T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	Tissue Bank staff do not record the reason for disposal in the tissue log. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	Freezer monitoring software is currently being updated. The DI is advised to coordinate the updating of the Tissue Bank Operating Manual, to reflect the revised procedure for monitoring and visualising the freezer temperature data, with the adoption of the new software.
2.	GQ2(a)	The DI conducts regular audits of the total numbers of stored samples and consent forms. To strengthen traceability auditing, the DI is advised to implement an audit process to reconcile consent documents with their associated samples.
3.	GQ4(b)	During the inspection, the HTA received oral assurance that electronic records are backed up daily by the University. The DI is advised to document the process.
4.	T1(c)	To further strengthen traceability, the DI is advised to consider implementing a consistent process to document and track any consent limitations associated with stored samples across all projects; for example, when there are time limitations for the storage of samples in longer term studies or limitations on the use of imported samples.

5.	T1(c)	The establishment's tissue log documents when material is removed from, and returned to, storage. Several examples were noted where material was removed and records indicated it should be returned to storage, but was not. Individual project records confirmed the fate of the material and ensured that an audit trail was maintained. The DI is advised to amend the tissue log to ensure that the fate of all tissue removed can be clearly identified; this information could also be reviewed as part of the scheduled Tissue Bank audits.

Background

The establishment's premises are located within the Faculty of Health and Life Sciences. The establishment's Tissue Bank stores relevant material for research studies undertaken by academic researchers, PhD and undergraduate students. At the time of the inspection, the Tissue Bank stored relevant material for 24 active research studies.

Northumbria University has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in August 2016. The establishment changed the Corporate Licence Holder contact in 2020. No other significant changes have been made to the licence since the last inspection.

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
Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing staff training, adverse events, incidents and audits were also reviewed.

Visual inspection
No visual inspection was undertaken as part of this inspection. As part of the assessment, digital images of the -80˚C and -20˚C freezer units storing relevant material were provided for review.

Audit of records
Records from the establishment's most recent internal audit were reviewed and discussed. In addition, the traceability records for samples removed from and returned to storage were reviewed for three studies.

Meetings with establishment staff
The inspection included discussions with the DI, the Assistant Director of Faculty Operations, the Technical Manager for Nursing and Life Sciences, three academic Principle Investigators and staff carrying out processes under the licence.

Report sent to DI for factual accuracy: 15 February 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 28 February 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 Virtual Regulatory Assessment Report.

Date: 28 February 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 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.