Inspection report on compliance with HTA licensing standards
Inspection date: **16 February 2022**

The Medical School, Newcastle University

HTA licensing number 12534

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: The Medical School, Newcastle University	Licensed	Not licensed
Satellite site: Institute of Genetic Medicine – International Centre for Life (Newcastle University)	Licensed	Not licensed
Satellite site: Institute of	Licensed	Not licensed

Neuroscience – Edwardson Building, Campus for Ageing and Vitality (Newcastle University)		
Satellite site: Institute of Transplantation and Northern Centre for Cancer Care (Freeman Hospital)	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.

The Medical School, Newcastle University ('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(d)	Joint governance meetings, involving DIs across different sectors, are a feature in several other organisations that hold multiple HTA licences.

		Newcastle University is Corporate Licence Holder (CLH) on two HTA licences and the CLH contact (CLHc) is the representative on both licences. There are currently no meetings between DIs and individuals named on these licences. The DI and CLHc are advised to consider setting up joint governance meetings involving staff on both licences, as opportunities for shared learning and to help ensure consistency of practices.
2.	GQ5(b)	Adverse events and actions taken are recorded inconsistently. The DI is advised to formalise the processes of recording adverse event findings, documenting discussions about adverse events, conducting root cause analyses and capturing the resulting corrective and preventative actions.
3.	PFE2(c)	The establishment has a continuous temperature monitoring system for its storage units. The DI is advised to consider regular challenging of the temperature alarm callout system and the audible temperature alarms to ensure that they function as expected. In addition, the DI is advised to consider initiating a programme by which, at suitable intervals, the temperature plots from the freezers are reviewed. This may help to identify a potential failure of the equipment before it occurs.
4.	PFE2(c)	Five of the Research Tissue Banks and five of the Research Centres contain either formalin-fixed tissue or formalin-fixed paraffin wax-embedded blocks and sections at ambient temperature; these storage areas are not temperature-monitored. Excessive or prolonged raised temperatures in these areas may lead to biomarker degradation. The DI is advised to assess the risks of these current arrangements and consider the effects that storage temperature deviations could have on the integrity of the samples stored.
5.	PFE3(a)	The DI is advised to ensure that all storage unit maintenance and probe calibration contracts are kept up to date. This will help to provide assurances that equipment remains suitable for use.

Background

The Medical School, Newcastle University contains 12 NHS Research Ethics Committee (REC)-approved, HTA-licensed Research Tissue Banks (RTBs) containing relevant material from living and deceased donors. Six of these are at the hub and six are at the satellites. They receive relevant material from hospitals, collaborators and expired clinical trials both nationally and internationally. Relevant material is obtained from both patients and healthy volunteers. The establishment also stores relevant material from living donors in six Research Centres under the licence. At the time of the inspection, relevant material from 79 collections was being stored in these Centres.

The University amalgamated its four separate research licences into one unified licence covering the establishment licence in July 2009. This was the second inspection of the establishment; the last one took place in April 2011.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in 2016, the current CLHc was registered with the HTA in 2016, 13 Persons Designated (PDs) have been added to the licence (and 21 removed). Two satellites were removed from the licence in 2014 and 2016.

Description of inspection activities undertaken

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

Standards assessed against during inspection

There are 47 standards under the Human Tissue Act 2004 ('HT Act'). One standard is not applicable as the establishment does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed, temperature monitoring records, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, minutes of meetings, the management of complaints, staff training records, and risk assessments.

Four of the establishment's internal audits and five reported adverse events were reviewed.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

No formal audit of records was carried out by the HTA.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, CLHc, nine PDs (including those based at the hub and two of the satellites), one Senior Biomedical Scientist and two Research Technicians. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 16 March 2022

Report returned from DI: 23 March 2022

Final report issued: 20 April 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.