Inspection report on compliance with HTA licensing standards
Inspection date(s): **17 & 20 January (remote) and 22 & 23 January (site visit) 2025**

University of Nottingham

HTA licensing number 12265

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 University of Nottingham	Licensed	Not licensed
Satellite University of Nottingham (Sutton Bonnington campus)	Licensed	Not licensed
Satellite Royal Derby Hospital	Licensed	Not licensed
Satellite Nottingham City 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.

Although the HTA found that University of Nottingham ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against Governance and quality system standards. These related to the review of standard operating procedures (SOPs) and the distribution of risk assessments.

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.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities	At the time of the inspection, the establishment was undertaking a large project to upgrade the governance systems relating to licensed activities. These upgrades include a new quality management system. As a full review of documents was being carried out but had not been completed, some of the SOPs were overdue review.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Staff can access risk assessments and are made aware of risks during training	Although research groups are required to complete risk assessments relating to licensed activities, not all staff involved in licensed activities were aware of the documents.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The 'Consent for Donation and Use of Human Tissue' SOP (HTMG SOP 003) provides information in section 4.4.4 on what to do if the potential donor does not have capacity to consent for themselves. The DI is advised to reference how the provisions of the Mental Capacity Act 2005 (MC Act) should be applied. Further information is available in paragraphs 114-127 of the HTA's Code of Practice on Consent (Code A).
2.	C1(a)	The 'Consent for Donation and Use of Human Tissue' SOP (HTMG SOP 003) details a consent exception

		where the tissue is supplied without donor identification and the research is taking place under recognised research ethics committee (REC) approval. The DI is advised to include that the material must also be from a living person for the exception to apply.
3.	C1(a)	The 'Consent for Donation and Use of Human Tissue' SOP (HTMG SOP 003) states that consent form templates for research are available from the HTA website. The HTA does not provide any template consent forms for research and therefore the DI is advised to amend this wording.
4.	C2(a)	For clarity, the DI is advised to include information about the training requirements for consent seekers within the 'Consent for Donation and Use of Human Tissue' SOP (HTMG SOP 003).
5.	GQ1(a)	The 'Human Tissue Research Management Policy' gives a summary of the licence arrangements within section 4.3. The DI is advised to provide details of the three satellite licenses as currently it only refers to 'University of Nottingham' premises.
6.	GQ1(b)	The establishment intends to review policies and SOPs every three years. As many of the documents are new - as part of the upgrade project - the DI is advised to consider reviewing them more frequently, at least initially.
7.	T1(c)	To ensure that staff are aware of the necessity to maintain sample quality, safety and security, the DI is advised to consider improving signs on the freezers highlighting that human samples are contained within.
8.	T2(a)	There is a small collection of spines, stored following a biomechanics study. The PD confirmed that the collection is no longer stored for research and is awaiting disposal. The DI is advised to facilitate the transfer of this collection to the anatomy department that intends to carry out the sensitive disposal as soon as possible. If, longer storage is required, the DI is advised to review the current storage conditions and consider improving the packaging and labelling of the specimens. Currently some spines are stored in non-sealed plastic bags with identifiers poorly written on in marker pen.
9.	PFE1(b)	Most of the laboratories are secured using a key code locking system. Staff confirmed that the key code is changed annually at most of the sites, however staff were unaware of the code being changed in the laboratory

		within the Clinical Sciences Building at Nottingham City Hospital. The DI is advised to change access codes periodically to help ensure that security is maintained.
10.	PFE3(a)	There was a build-up of frost on one of the freezers that was audited in the Clinical Sciences Building at Nottingham City Hospital. This was due to a damaged door seal. The PD reassured the inspection team that repair was being organised. The DI is advised to follow up on this to ensure that the required maintenance is completed before sample storage could be compromised.

Background

University of Nottingham has been licensed by the HTA since August 2007. This was the third inspection of the establishment; the most recent inspection was a virtual assessment and took place in May 2022.

Since the previous inspection, there have been some significant changes to the personnel named on the licence including the Designated Individual (DI) in September 2022 and the Corporate Licence Holder contact (CLHc) in December 2024.

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 (SOPs) were reviewed. Documents detailing staff training, internal audits, risk assessments, meeting minutes and incidents were reviewed, as well as consent-seeking procedures and information used to support the seeking of consent from donors for research projects.

Visual inspection

The inspection team undertook a site visit inspection of the hub site at University of Nottingham (Queens Medical Centre and University Park) and the satellite sites at Derby Hospital, Nottingham City Hospital and the University of Nottingham campus at Sutton Bonnington. The inspection included visits to the laboratory areas, storage facility areas and the office areas where paper records are stored.

Audit of records

Traceability audits were carried out for samples stored for 15 collections held under the licence. The audits included a variety of samples, stored in different conditions, taken from living and deceased donors. Traceability details were cross-checked between the identification details on the samples, information on the electronic and paper records and the associated consent forms (if relevant). Audits were also carried out for samples which had been used for research and disposed of after use. All samples audited were fully traceable.

Meetings with establishment staff

The assessment included discussions with the Technical Team, the Quality Team, and academics involved in research including Researchers, Professors, Research Fellows, Engineers and an Associate Professor (who holds the position of DI).

Report sent to DI for factual accuracy: 30 January 2025

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

Final report issued: 12 February 2025

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.