Inspection report on compliance with HTA licensing standards
Inspection date: **9 May 2022**

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
University of Nottingham, Queen's Medical Centre (Hub)	Licensed	Not licensed
Nottingham City Hospital (satellite)	Licensed	Not licensed
Royal Derby Hospital (satellite)	Licensed	Not licensed
University of Nottingham, Sutton Bonnington Campus (satellite)	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.

University of Nottingham ('the establishment') was found to have met most of the HTA's standards; however, two minor shortfalls were identified against standards for Consent (training of non-clinical staff) 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 assessment.

Compliance with HTA standards

Standard	Visit Findings	Shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	Only clinical staff involved in seeking consent for HRA-approved studies have demonstrable consent training. Currently, there is a process for checking that non-clinical staff seem competent to seek consent and there are plans to develop formal consent training for non-clinical staff.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	The freezers have audible alarms, and there is a call-out system which notifies members of staff if there is a problem detected during regular hours and out-of-hours, but there is no regular temperature monitoring.	**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.	HTA SOP 005, Disposal of Human Tissue does not detail the requirement to document the reason, method and date of disposal. Multiple research groups refer to this overarching SOP which could lead to varying documentation practices and the risk of omitting this requirement.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(c)	The establishment occasionally purchases relevant material from external providers. The DI is advised to consider adopting a system of maintaining a list of pre-approved providers of relevant material should the purchase of relevant material for storage for a scheduled purpose under the HT Act happen more regularly. This will enable staff to ensure that only material with appropriate consent in place is supplied to the establishment.
2.	GQ1(a)	The establishment uses overarching SOP templates which each research area has adapted for its specific use. The DI is advised to consider reviewing the overarching SOP 006 as it states that the date of birth and the

		initials should not be used as part of the sample traceability; however, for certain research groups, it is common practice to use this naming convention. The DI should consider reviewing and revising SOP 006 to ensure it reflects actual practices.
3.	GQ2(a)	The DI and Human Tissue Management Group Quality Manager have a robust and comprehensive approach to auditing licensable activities. There are annual audits of each research group and themed audits are used to explore specific areas further. The DI may wish to consider reviewing the frequency of these audits and whether Persons Designated (PDs) could be involved in auditing one another's respective research areas, enabling auditing to take place more regularly and also widening the pool of staff involved in this process.
4.	GQ5(a)	There are clear processes and procedures in place for the reporting of adverse events; however, the DI may wish to consider expanding the examples of reportable events so that staff are aware of those which may be relevant to HTA-licensed activities. These could include but would not be limited to: • specimen loss • missing or incorrect documentation • security breaches • abnormalities in storage temperature readings • inappropriate disposal.
5.	GQ6(a)	Each research area is responsible for undertaking their own assessments of risks relating to licensable activities. To strengthen risk assessments further, the DI is advised to work with PDs to review their risk assessments to ensure all mitigations are consistently presented.
6.	T1(a)	High levels of research activity take place across the hub and satellite sites, with each research area having a PD under the licence who reports to the DI. The DI may wish to consider implementing a centralised system to

		support traceability, as opposed to each group maintaining traceability records. This may help to improve the accessibility of this information to the DI.

Background

Research material is stored as the hub (The University of Nottingham) and three satellite sites. The establishment stores a range of different tissues, from living and deceased donors, for studies that have been approved by either a recognised (HRA) research ethics committee (REC) or the University REC.

This was the second inspection of the establishment; the most recent previous inspection took place in 2011.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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

All 47 standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to, standard operating procedures for licensable activities, key policies, study audits including an audit against HTA standards, meeting minutes, staff training records, traceability records and incidents.

Visual inspection

There was no visual inspection of the premises; however, a meeting took place with relevant staff members to discuss the PFE standards.

Audit of records

No traceability audits were carried out; however, a review of the establishment's audits was undertaken as part of the assessment. The DI carries out an extensive audit of each area, reviewing the audits carried out by each of the research groups -with a particular focus on record completeness - and then carrying out a traceability audit of samples in storage. The Inspector had no concerns with the reports presented during the assessment.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff and included the DI and PDs involved with licensed activities.

Report sent to DI for factual accuracy: 27 May 2022

Report returned from DI: 3 June 2022 (with comments)

Final report issued: 9 June 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 Inspection Report.

Date: 04 November 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.