Inspection report on compliance with HTA licensing standards
Inspection date(s): **6 February 2025**

University of Ulster

HTA licensing number 12064

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 Ulster	Licensed	Not licensed
Satellite Belfast Campus	Licensed	Not licensed
Satellite University of Ulster – York Street	Licensed	Not licensed
Satellite Altnagelvin Area 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 Ulster (‘the establishment’) had met the majority of the HTA’s standards, three minor shortfalls were found against Consent and Governance and quality system standards. These related to the competency assessments for consent seekers, internal audits of collections held under the licence and the review 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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained	Staff involved in the consent-seeking process are trained; however, competency is not formally assessed.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	The establishment is not up-to-date with the audit schedule and many collections held under the licence have either not been audited or have not been audited for many years.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments are reviewed regularly	The establishment's overarching risk assessment relating to licensable activity is not reviewed regularly.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	Consent procedures are documented within the establishment's 'Consent SOP' but the training that is required for staff seeking consent is not documented. The DI is advised to include information on the consent training – including the expected frequency of training - within this document.
2.	GQ1(a)	The storage SOP (SOP006) details the requirements of the licensed storage facilities in relation to security,

		maintenance, monitoring and capacity. The document is brief in some areas and to ensure that written procedures reflect actual practices, the DI is advised to consider including the following information within the document: • How the remote temperature monitoring alarm and call-out system is managed • The contingency arrangements, including the empty contingency facilities at each of the sites • The signage to be included in storage areas • That animal and human material is stored separately
3.	GQ1(b)	There is limited document control on the establishment's overarching risk assessment relating to licensable activities. Taking into account the response to the shortfall identified against GQ6(b), the DI is advised to include the revision history, version number, review date and reviewer name(s) on the document.

Background

University of Ulster has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent inspection was an evaluated self-assessment and took place in October 2023. Since the previous inspection, there have been no significant changes to the licence arrangements.

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

46 of 47 HTA licensing standards were covered during the licence assessment (standards published 3 April 2017). PFE2(b) was not relevant as the establishment does not store deceased donors.

Review of governance documentation
Policies and procedural documents relating to all licensed activities were reviewed. This included overarching standard operating procedures (SOPs), risk assessments, meeting minutes and audits. Information relating to the establishment's consent-seeking procedures and information used to support the seeking of consent from donors for research projects was also reviewed.

Visual inspection
There was no site visit inspection associated with the assessment.

Audit of records
As there was no site visit inspection associated with the assessment, internal audits for five randomly selected collections held under the licence were requested. Four of the collections have not been audited, and one collection was last audited in 2018 (see shortfall under GQ2(a)).

Meetings with establishment staff
The assessment included discussions with the Research Governance Manager, Head of Research Governance, Director of Research and Innovation and a Lecturer (who holds the position of DI).

Report sent to DI for factual accuracy: 20 February 2025

Report returned from DI: 24 February 2025

Final report issued: 26 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.