Inspection report on compliance with HTA licensing standards
Inspection date(s): **15 April (remote) and 16 April (site visit) 2024**

University of Chester – Bache Hall

HTA licensing number 12745

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 Chester – Bache Hall	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 Chester – Bache Hall ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems and Traceability.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose	During the traceability audit, there was no consent form available for one of the donations. Missing consent forms had also been identified in the recent internal audits. As the collection had been obtained from a third party, the establishment was in contact with researchers and centres where the samples were collected to obtain the associated paperwork.	**Minor**
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	The HTA001 *Policy on the Use and Storage of Human Material for Research Purposes* contained some inaccurate statements, including: • Paragraph 7.2 - *'Existing material collections (collected before the 1st September 2006) can be stored without a licence'.* • Paragraph 7.3.1 - *'The process of culturing primary human cells into secondary cell cultures/cell lines for the purpose of research, is required to take place on HTA licenced premises'.* Furthermore, although there were policy and procedural documents to govern new and future research projects, there were no policy or procedural documents to cover acquired research collections. Since the licence was granted, one research collection of approximately 11,000 samples had been acquired. There were no documents detailing how the establishment accepted and was to manage the collection to ensure that it met the regulatory and legal requirements, including the HTA's licensing standards.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	A large research collection was obtained under the licence in July 2023 however this has not been fully audited to ensure that specimens and records are fully traceable from consent to storage.	**Minor**
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and the associated products where relevant, is maintained	During the traceability audit, only paper records were available for one of the donations, and the records did not detail the number of samples that were stored. This had also been identified in the establishment's recent internal audits.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	There are some duplications in the establishment's SOPs relating to licensable activities. The DI is advised to amalgamate the SOPs that overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.
2.	GQ1(a)	Documents, including SOPs, are only redistributed to staff if changes are made during the review process (which occurs every three years). The DI may wish to consider redistributing regardless of whether there have been changes made to ensure that staff are fully trained and up-to-date on policies and procedures relevant to their work.
3.	GQ1(b)	A templated consent form and patient information sheet are available to researchers planning research projects. These documents are not version-controlled. The DI is advised to include version control within the documents to ensure that the most up-to-date versions are used.

4.	GQ1(c)	Staff have access to the establishment's main SOPs relating to licensable activities. There is a table at the end of each document where staff can sign to record that they have read and understood the document. The tables are not used. To further strengthen change control, and ensure staff are up-to-date with procedures, the DI is advised to implement a procedure that confirms staff have read and acknowledged the current versions of documents.
5.	GQ2(a)	Although appropriate consent has been given for donated samples in the research collection held under the licence, some consent forms are completed as expected; for example, the consent-seeker's name is missing and some have ticks in the check boxes instead of being initialled as per instructions. Although the establishment is not responsible for obtaining consent, it has responsibility to ensure valid and appropriate consent has been obtained for the samples it has received. The DI is advised to ensure that the audit schedule includes vertical audits of records and samples, from sample through to consent documentation. Records should be audited regularly to ensure completeness, accuracy and legibility.
6.	GQ6(b)	Risk assessments are reviewed every three years. As the University plans to increase research activities, including projects that use relevant material, the DI is advised to review the risk assessments more frequently to ensure that they are kept up-to-date with the changes.

Background

University of Chester – Bache Hall has been licensed by the HTA since January 2023. This was the second inspection of the establishment; the most recent inspection was the licence application assessment that took place in August 2022.

Since the previous inspection, there has not been any 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

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

Visual inspection

The Regulation Manager undertook a site visit inspection of Bache Hall which included the laboratory area where samples are stored and the office area where paper records are stored.

Audit of records

Traceability audits were carried out for samples within the one research collection held under the licence. The audit included 110 samples taken from 10 donors. Traceability details were cross-checked between the identification details on the sample vials, information on the electronic and paper records and the associated consent forms. For one of the donations audited, the consent form was missing and there were no records of the number of samples stored for that donor (see Shortfalls under C1(b) and T1(b).

Meetings with establishment staff

The assessment included discussions with the Head of Applied Medicine, the Head of Medical Science, a Senior Lecturer, the Deputy Vice Chancellor (who holds the position of Corporate Licence Holder contact, CLHc) and an Associate Professor (who holds the position of DI).

Report sent to DI for factual accuracy: 22 April 2024

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

Final report issued: 3 May 2024

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.