Inspection report on compliance with HTA licensing standards
Assessment date: **06 June (remote) and 09 June (site visit) 2022**

University of Bristol

HTA licensing number 12135

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical examination	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	Storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
University of Bristol	Licensed	Licensed	Licensed	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 the University of Bristol (the 'establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems (risk assessments) 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 assessment.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The establishment does not have a risk assessment that covers the risk/s of storing and using specimens retained for further use without appropriate and valid consent.	**Minor**

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	A unique code is assigned to each donation and its parts for the teaching specimens in the Anatomy school. However, there is no system to uniquely identify any body parts removed from fresh frozen cases that are used in surgical skills training (Vesalius Clinical Training Centre).	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	GQ1(a)	To strengthen governance and consistency in carrying out procedures, the DI is advised to put in place a formalised system to record that administration staff have read and understood SOPs.

2.	GQ2(a)	Regular horizontal and vertical audits are carried out by establishment governance staff. The DI is advised to consider including procedural audits in this schedule to ensure that all practices fall under the establishment's ongoing monitoring.
3.	GQ6 (a)	Establishment staff have identified new commercially available equipment that may make the positioning and handling of bodies easier and safer during training courses. Formal risk assessment methodology may assist the selection and procurement process.

Background

University of Bristol (the 'establishment') undertakes a wide range of activities, including anatomy courses for students and surgical skills training courses for health professionals. The establishment stores, prepares and uses embalmed specimens and fresh frozen bodies and body parts. They also store a collection of potted specimens and skeletal material which is used for training and education purposes.

This was the third inspection of the establishment, the last one took place in October 2015.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was approved in 2022 and a Persons Designated (PDs) was added to the licence in 2021.

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 assessment:

Standards assessed against during the inspection

All HTA licensing standards were covered during the assessment (standards published 3 April 2017).

Review of governance documentation

The following documents were reviewed: donor consent forms and information provided to potential donors, policies and procedural documents relating to licensed activities, audits, risk assessments, adverse incidents, staff training records, visitor management policies and student and delegates codes of conduct.

Visual inspection

A visual inspection was conducted of areas where relevant material is stored, areas where training and dissection are carried out and designated areas for body preparation.

Audit of records

Traceability audits were conducted for three bodies and their associated parts, two retained specimens, one potted specimen and one box of skeletal remains. This included the location of the specimens, consent forms, electronic records and paper records. No discrepancies were found.

Meetings with establishment staff

The inspection included discussions with the staff carrying out processes under the licence. This included the CLHc, the DI, a PD, Head of School for Anatomy, Head of Research and Governance, managers for research and human tissue, managers of the dissection suite, and specialist technicians.

Report sent to DI for factual accuracy: 21 June 2022

Report returned from DI: 28 June 2022

Final report issued: 6 July 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: 3 October 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 site visit 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 site visit.

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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.