Inspection report on compliance with HTA licensing standards
Inspection date: **27 April 2022**

Biomedical Sciences Building, University of Bristol

HTA licensing number 12248

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
Biomedical Sciences Building, University of Bristol	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.

The Biomedical Sciences Building, University of Bristol (the 'establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C2(a)	Current training in the seeking of consent involves undertaking Good Clinical Practice (GCP), reading specific standard operating procedures (SOPs) and shadowing experienced staff. The DI is advised to consider formalising these expectations in a training, and refresher training, programme. This may help to strengthen consistency and demonstration of consent training for new and existing staff.
2.	GQ2(a)	Regular horizontal and vertical audits are carried out by establishment laboratory and 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.	GQ5(b)	Adverse events and actions taken are recorded inconsistently. The DI is advised to formalise the processes of recording adverse event findings, documenting discussions about adverse events, conducting root cause analyses, and capturing the resulting corrective and preventative actions.
4.	PFE1(c)	There are documented cleaning and decontamination SOPs but cleaning and decontamination is not recorded consistently. The DI is advised to consider setting up a formal schedule to record cleaning and decontamination of

		both facility and storage units.
5.	PFE2(c)	The establishment has a continuous temperature monitoring system for its storage units. The DI is advised to consider initiating a programme by which, at suitable intervals, the temperature plots from the freezers are reviewed. This may help to identify a potential failure of the equipment before it occurs.
6.	PFE3(a)	Storage units and temperature probes are subject to regular maintenance by external contractors. The DI is advised to consider keeping a record of contractor service reports to ensure that storage unit and temperature probe performance is regularly monitored.

Background

The Biomedical Sciences Building, University of Bristol contains one NHS Research Ethics Committee (REC)-approved, HTA-licensed RTB containing relevant material from living donors. It receives material nationally from hospitals and academic and commercial collaborators. Additionally, the RTB stores relevant material from expired project-specific, REC-approved studies. The material is obtained from both patients and healthy volunteers. The establishment also stores relevant material from living and deceased donors for 26 research groups. At the time of the inspection, relevant material from 41 collections was being stored. Approximately 90% of these have current project-specific REC approval, and the storage of these samples is exempted from HTA licensing. The remaining studies are overseen by the Research Governance Team.

The establishment also stores existing holdings from deceased donors used for education and training purposes. This includes formalin-fixed paraffin wax-embedded blocks and sections (the Histology Teaching Collection) and formalin-fixed tissue (the Anatomy Teaching Collection). The material is used for the teaching of undergraduate and postgraduate medical, dental and veterinary students, biomedical science students and healthcare professionals.

The establishment has been licensed by the HTA since July 2007. 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 registered with the HTA in 2022, two Persons Designated (PDs) have been added to the licence and one satellite was removed from the licence in 2015.

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

46 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). One standard is not applicable as the establishment does not store bodies or body parts [standard PFE2(b)].

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed, temperature monitoring records, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, minutes of meetings, the management of complaints, staff training records, and risk assessments.

Five of the establishment's internal audits and one recorded adverse event were reviewed.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

No formal audit of records was carried out by the HTA.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, CLHc, three PDs, two Research and Human Tissue Managers, the Head of Research Governance, the Faculty Manager, and a Senior Executive Assistant. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 26 May 2022

Report returned from DI: 7 June 2022

Final report issued: 30 June 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.