Inspection report on compliance with HTA licensing standards
Assessment date: **19 October 2021**

University of Bradford

HTA licensing number 12191

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 Bradford	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 the University of Bradford (the 'establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Consent, and Premises, facilities and equipment.

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
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		
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.	Two of the six agreements with supplying hospitals do not include confirmation that consent has been obtained.	**Minor**

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required	Temperature monitoring of the storage cabinets which contain formalin-fixed tissue and formalin-fixed paraffin wax-embedded blocks and sections at ambient temperature is not carried out. Excessive or prolonged raised temperatures in these rooms may lead to biomarker degradation. Additionally, it was identified that two -80°C freezers were not covered by the continuous temperature monitoring system. For these units, there is no risk assessment to cover the potential for there to be a storage temperature deviation over the weekend, when no staff are in attendance.	**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.	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.
2.	GQ2(b)	Audit findings and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording audit findings, discussions about the audit, who is responsible for follow-up actions and the timeframes for completing these.
3.	GQ5(b)	Adverse events and actions taken are recorded inconsistently. The DI is advised to formalise the process of recording adverse event findings, discussions about the adverse event, root cause analysis and resulting corrective and preventative actions.
4.	T1(c)	There are detailed tissue registers covering the traceability of stored samples. To ensure that the licensing requirement for each tissue sample is clear, the DI is advised to consider identifying which samples have been received from external RTBs; these will be covered by that RTB's licence.
5.	PFE3(a)	Storage units are subject to regular maintenance by internal contractors. The DI is advised to consider keeping a detailed record of contractor service reports to ensure storage unit performance is regularly monitored.

Background

The University of Bradford contains an NHS REC-approved, HTA-licensed Research Tissue Bank (RTB). The establishment also stores relevant material from five research groups on campus, from living and deceased donors. At the time of the inspection, relevant material from 30 collections was being stored. Approximately half of these have current UK Ethics Committee Authority (UKECA) approval, NHS Research Ethics Committee (REC) project-specific approval or are covered by RTB REC approval, and the storage of these samples is exempted from HTA licensing. The remaining studies fall under the licence.

The establishment has been licensed by the HTA since September 2007. This was the second inspection of the establishment, the last one took place in September 2009.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current DI was approved in August 2018, the current Corporate Licence Holder contact (CLHc) was registered with the HTA in December 2019 and 10 Persons Designated (PDs) have been added to 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 assessment:

Standards assessed against during the inspection

All 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).

Review of governance documentation

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

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

Five of the establishment's internal audits were reviewed. Advice is provided about the management of audits (see *Advice*, item 2).

Two reported adverse events were reviewed. Advice is provided about the management of adverse events (see *Advice*, item 3).

Visual inspection

There was no site visit associated with this inspection.

Audit of records

As there was no site visit associated with this inspection no formal audit of records was carried out.

Meetings with establishment staff

The inspection included meetings with the following staff: DI, CLHc, two PDs, RTB manager, a Research Nurse and a Senior Scientist. The meetings covered: consent, distribution and disposal procedures; quality management, document control, governance meetings, staff training; audits/traceability, incidents/complaints, risk assessments; premises security, facilities and equipment maintenance, storage temperature monitoring and contingency arrangements.

Report sent to DI for factual accuracy: 10 November 2021

Report returned from DI: 10 November 2021

Final report issued: 21 December 2021

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 Virtual Regulatory Assessment Report.

Date: 22 February 2023

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.