Inspection report on compliance with HTA licensing standards
Inspection date: **18 January 2023**

University of Brighton

HTA licensing number 12583

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 site **School of Applied Sciences**	Licensed	Not licensed
Satellite site **Welkin Science Laboratories**	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 Brighton ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Consent (training records) and Governance and quality systems (document coverage and audit handling).

Compliance with HTA standards

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		
b) Records demonstrate up-to-date staff training.	A Principal Investigator (PI) trained third party volunteers in consent taking for a research project but no records were available to demonstrate this training had been completed.	**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.	There was no standard operating procedure (SOP) for the collection of all samples of relevant material. In addition, the Transport and Receipt of Human Tissue SOP did not fully document the actions and processes to be undertaken when receipting relevant material at the establishment.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	Internal audit findings are logged as adverse incidents and a CAPA plan has to be completed within two weeks. However, there were no timeframes for completing the follow-up actions identified.	**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.

DI Suitability

The HTA found the Designated Individual (DI) to be suitable in accordance with the requirements of the legislation.

Advice

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

Number	Standard	Advice
1.	C1(d)	The DI is advised to update Participant Information Sheets with a statement to include relevant material may be exported for use abroad where applicable.
2.	C2(a)	To build on and further strengthen current training requirements for consent seekers the DI is advised to provide the HTA Code of Practice A ‘Guiding principles and the fundamental principle of consent’ and Code E ‘Research’ to staff as part of consent training.
3.	GQ1(a)	The DI is advised to include, within the Withdrawal of Consent SOP, a process step pertaining to the removal of relevant material from the tissue tracking database when consent is withdrawn to strengthen traceability.

4.	GQ1(a)	The DI is advised to formalise the process for challenging temperature alams within the relevant SOP and ensure the contact details for alarm responders are current.
5.	GQ1(c)	There are change control mechanisms in place for the implementation of new operational procedures but the DI is advised to implement a process to ensure new and amended SOPs have been read and understood.
6.	T2(b)	The DI is advised to consider an option to indicate a donor has withdrawn their consent in the list for relevant material disposal reasons in the tissue tracking database.
7.	PFE1(c)	Although there is an SOP in place for the cleaning and decontamination of storage areas, there was no evidence of cleaning being undertaken at the satellite site and the DI is advised to ensure this is carried out as expected and documented.

Background

Relevant material is obtained from living patients, either during clinical consultations at another HTA-licensed establishment or by healthy volunteers recruited for research studies through the university. Relevant material is stored for the scheduled purpose of 'Research in connection with disorders, or the functioning, of the human body' ('research').

The University of Brighton has been licensed by the HTA since 2011. This was the second inspection of the establishment; the most recent previous inspection took place in March 2013.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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

Review of governance documentation
The inspection comprised a review of documentation relevant to the establishment's licensed activities including; policies and procedural documents, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, a review of the Tissue Tracking Database, staff training records, temperature monitoring for the storage units and audits.

Visual inspection
No site visit was undertaken as part of this inspection. However, the establishment provided photographs and video of the storage facility and security arrangements.

Audit of records
Recent location and project specific audits were reviewed as part of this inspection. These audits and their findings were reviewed against the electronic Tissue Tracking Database.

Meetings with establishment staff
The inspection included virtual meetings with the DI and the Human Tissue Governance Manager. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 10 February 2023

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

Final report issued: 3 March 2023

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: 2 June 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 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.