Inspection report on compliance with HTA licensing standards
Inspection date: **27 April 2023**

# University of Plymouth

HTA licensing number 12103

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:**<br>University of Plymouth Peninsula Schools of Medicine and Dentistry<br><br>**Satellite Site:**<br>Davy Building and Link 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 Plymouth ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for 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 inspection.

**Compliance with HTA standards**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
| a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. | The temperature probes to monitor the relevant material storage areas were not subject to calibration. | **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) | The DI is advised to amend UOP HTA Standard Form 1.0: Transfer of Human Tissue into the University of Plymouth within SOP08 Tissue Transfer to include a link to SOP05 Adverse Events so users are aware that any logged incident which may affect the safety or integrity of relevant material is to be raised as an adverse event for investigation. |
| 2. | GQ1(a) | The DI is advised to amend SOP04 Disposal of Surplus or Unusable Human Relevant Material to specify the disinfectant to be used to neutralise larger volumes of fluid containing cellular material to ensure uniformity of practice. |
| 3. | GQ2(a) | Scheduled audits are undertaken at a regular frequency. The DI is advised to consider including a regular audit against HTA standards to demonstrate compliance with HTA licensing requirements. |
| 4. | GQ5(a) | Staff are instructed in how to report adverse events and these are recorded in a spreadsheet. To manage incidents in one database, the DI is advised to consider whether the establishment's Incident Management System can be utilised to record adverse events and any corrective and preventative actions taken. |

**Background**

The majority of human tissue samples held by the establishment are stored and used in projects with approval from recognised research ethics committees (RECs). A limited number of samples held under this licence are stored for the scheduled purpose of research in connection with disorders, or functioning of the human body and education or training relating to human health.

The University of Plymouth has been licensed by the HTA since March 2010. This was the second inspection of the establishment; the most recent previous inspection took place in December 2012.

Since the previous inspection, there have been no significant changes to the licence arrangements and the establishment now operates two biobanks.

**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 does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

*Review of governance documentation*

The inspection covered a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents, equipment servicing records, risk assessments, minutes of meetings, a review of the traceability database, monitoring of storage conditions, training records and audits.

*Visual inspection*

No site visit was undertaken as part of this inspection. However, the establishment provided extensive videos of the storage facility and their security arrangements.

*Audit of records*

The establishment's traceability database was reviewed and checked with samples from receipt and storage location through to use or disposal.

*Meetings with establishment staff*

The inspection included virtual meetings with the following staff: the Designated Individual (DI), two Persons Designated (PD), a representative from the Research Governance Office and a University HTA Sponsor. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

**Report sent to DI for factual accuracy: 23 May 2023**

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

**Final report issued: 7 June 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: 14 July 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.