Inspection report on compliance with HTA licensing standards
Inspection date: **06 December 2022**

# Middlesex University

HTA licensing number 12533

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 |
|---|---|---|
| **Middlesex University** | 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 Middlesex University ('the establishment') had met the majority of the HTA's standards, seven minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. The shortfalls were related to a lack of documented procedures and records, contingency planning, and maintaining a register of donated material.

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**

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **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. | The establishment had an overarching policy for collecting, receipting, labelling and transporting human tissue and undertaking audits but there were no documented standard operating procedures covering practices and processes. | **Minor** |

| | | |
|---|---|---|
| **GQ2 There is a documented system of audit** | | |
| a) There is a documented schedule of audits covering licensable activities. | The establishment had no documented schedule of audits. | **Minor** |
| b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these. | Audit findings are cascaded to staff but there was no evidence of a formalised audit follow-up process. | **Minor** |

| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills | | |
|---|---|---|
| a) Qualifications of staff and all training are recorded, records showing attendance at training. | The establishment undertakes annual training in relation to licensable activities but records of staff and student attendance were not maintained consistently. | **Minor** |

| T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail | | |
|---|---|---|
| b) A register of donated material, and the associated products where relevant, is maintained. | A register of donated material is kept at the establishment but it had not been updated and maintained on a regular basis with all pertinent data to allow full traceability. | **Minor** |

| T2 Bodies and human tissue are disposed of in an appropriate manner | | |
|---|---|---|
| b) The date, reason for disposal and the method used are documented. | The date, reason for disposal and/or the method of disposal of relevant material were not recorded in all instances. | **Minor** |

| PFE2 There are appropriate facilities for the storage of bodies and human tissue | | |
|---|---|---|
| d) There are documented contingency plans in place in case of failure in storage area. | The establishment has identified the risks and mitigating factors associated with a failure in the storage area, but have provided no documented contingency plans. | **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) and the Licence Holder (LH) 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 consent form supplied to donors states that a participant can withdraw their consent at any time. The DI is advised to make it clearer on the consent form to whom a withdrawal request should be addressed along with their relevant contact details. Currently there are sections on the consent form to record only the researcher's, the consent-seeker's (if different) and donor's name, signature and date. |
| 2. | GQ1(a) | The Adverse Event SOP provides relevant examples of adverse events and the DI is advised to include 'inappropriate disposal' as another example. |
| 3. | GQ1(b) | The DI is advised to reinstate the following features to each SOP to create a more robust system:<br>• document control information, such as a revision history and version number<br>• effective from date<br>• review date (at least every three years)<br>• issue date |

| | | |
|---|---|---|
| | | • pagination<br>• the names of both the author and the reviewer who has authorised the content of the document |
| 4. | GQ2(a) | The DI is advised to consider dividing the audit schedule into small increments, possibly carried out by different team members. This should include horizontal audits to ensure that SOPs accurately reflect current practices and vertical tissue traceability audits, from records of receipt to storage, use or disposal. The DI may also wish to consider implementing a regular audit against HTA standards. |

**Background**

Relevant material is stored for the scheduled purpose of 'Research in connection with disorders, or the functioning, of the human body' ('research'). The tissue collections are stored under secure conditions.

Middlesex University has been licensed by the HTA since January 2009. This was the second inspection of the establishment; the most recent previous inspection took place in June 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 does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

*Review of governance documentation*
The inspection included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, a review of the physical Human Material Tissue Log, and audits.

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

*Audit of records*
Recent internal 'stock check' audits were reviewed as part of this inspection.  These audits were reviewed against the electronic Human Material Tissue Log.

*Meetings with establishment staff*
The inspection included virtual meetings with the following staff: DI, Deputy DI, and two Persons Designated working under the licence. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

**Report sent to DI for factual accuracy: 20 December 2022**

**Report returned from DI: 12 January 2023**

**Final report issued: 20 January 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: 5 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.