Inspection report on compliance with HTA licensing standards
Inspection date: **8 February 2023**

Manchester Metropolitan University

HTA licensing number 12402

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
Manchester Metropolitan University **John Dalton Tower**	Licensed	Not licensed

Summary of inspection findings

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

Although the HTA found that Manchester Metropolitan University ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and quality systems (change control and risk assessments) and Premises, facilities and equipment (documented cleaning and decontamination procedures).

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		
c) There are change control mechanisms for the implementation of new operational procedures.	The establishment had no change control mechanisms for the implementation of new operational procedures, taking into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	There were no risk assessments relating to receiving and/or storing specimens without appropriate consent documentation and storing or using human tissue after consent withdrawal. Additionally, the transport of human tissue risk assessment coverered only the health and safety risks to people transporting the tissue and did not include wider risks relevant to the tissue. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures.	There were no documented cleaning and decontamination procedures for the HTA storage areas. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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)	Standard operating procedure (SOP) MMU HTA_003 Material Transfer states that relevant material can only be sent to other establishments that are licensed by their respective Competent Authority but there is no evidence these checks are being undertaken. For complete assurance and to meet the requirements set out in the SOP, these checks should be undertaken and documented.
2.	GQ1(a)	The DI is advised to expand the checklist (appendix 6) in SOP MMU HTA_010 for receipt of material to cover all areas to be checked for example including paperwork, sample loss in transport, and link it with adverse event reporting procedures to identify the actions taken to resolve any identified issues.
3.	GQ1(a)	The DI is advised to amend SOP MMU HTA_015 to include the challenge of temperature alarms that is undertaken to ensure the notifications and process of responding to alarms work as expected.
4.	GQ1(b)	The DI is advised to include the author and reviewer names on governance documentation.
5.	GQ2(a)	The DI is advised to create an audit template for the planned ‘themed’ audits to ensure relevant HTA licensable activites are assessed and covered consistently.
6.	GQ5(a)	The DI is advised to include all expected examples of adverse events within the SOP MMU HTA_002 to aid understanding of ‘reportable’ events and to include a step that clarifies timeframes for completing corrective actions.

Background

Healthy volunteers are mostly students based at the University, who are recruited and consented locally by researchers who have received consent training. The establishment has joint research projects with universities based in Europe and so occasionally imports and exports material from/to the

UK which are covered by appropriate material transfer agreements that cover details of appropriate consent and the use of the material for specific research projects.

Manchester Metropolitan University has been licensed by the HTA since June 2007. This was the second inspection of the establishment; the most recent previous inspection took place in February 2013.

Since the previous inspection, there has been a change of Designated Individual (DI) but no significant changes to 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 covered a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents, equipment servicing records, material transfer agreements, risk assessments, minutes of meetings, a review of the traceability database, training records 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

The establishment's new traceability database was reviewed and checked with samples from receipt to use or disposal, including associated Material Transfer Agreements and transport paperwork.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: DI, three Persons Designated working under the licence, the CLH, a member of the Human Tissue Research Ethic Governance committee and a Technical Officer. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 21 February 2023

Report returned from DI: 23 February 2023

Final report issued: 6 March 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.