Inspection report on compliance with HTA licensing standards
Inspection date: **20 June 2022**

University of Manchester

HTA licensing number 12172

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 University of Manchester	Licensed	Not licensed
Satellite Biocentre, North Campus	Licensed	Not licensed
Satellite Manchester Brain Bank	Licensed	Not licensed
Satellite Wolfson Molecular Imaging Centre	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 Manchester ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for Premises, facilities, and equipment, in relation to the temperature monitoring of critical storage areas.

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 shortfall identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

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	The freezer that is used for storage of material in the Early Pregnancy Research Tissue Bank has an audible alarm and is monitored twice weekly. As storage is considered to be critical, a purely local alarm and twice-weekly manual monitoring are not sufficiently robust protections.	**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.	C1(a)	Although the HTA was assured that consent is obtained from the most appropriate person (under the Human Tissue Act 2004) for donations to the Manchester Brain Bank, the DI is advised to review the consent documentation and remove potential confusing references to 'Next of Kin'.
2.	GQ1(a)	Although staff are required to be trained in seeking and obtaining consent, this is not detailed within the establishment's overarching consent policy, '*Guidance on Human Tissue Act 2004 consent requirements (UM/10/GD/HTA010)'.* The DI is, therefore, advised to document the requirements.
3.	GQ1(a)	Although temperature-controlled storage areas are monitored and alarmed, these requirements are not detailed within the establishment's overarching policy, *'Storage of human tissue samples (UM/10/SOP/HTA009)'.* The DI is, therefore, advised to document the requirements.
4.	GQ3(a)	Staff are required to complete online training relating to Human Tissue legislation prior to their involvement in licensable activity. As this training is a one-off event, the DI is advised to add refresher training to the schedule to ensure staff maintain their awareness and are kept up-to-date with legislation, published guidance and relevant policies.
5.	PFE1(b)	Slides for the Early Pregnancy Research Tissue Bank are stored within the microscope room. Although the premises are secure, the space is shared with researchers from other groups. The DI may wish to consider adding further security measures to the dedicated storage cabinet, such as a lock.
6.	PFE3(a)	Due to the COVID-19 pandemic, the routine maintenance schedule for some freezers has been disrupted. The DI is advised to ensure the annual schedule is reinstated.

Background

The University of Manchester has been licensed by the HTA since July 2007. This was the second inspection of the establishment; the most recent inspection took place in February 2011.

Since the previous inspection, there have been some significant changes to the licence arrangements, including the addition of three satellite premises - Biocentre, North Campus in 2011, Manchester Brain Bank in 2019 and the Wolfson Molecular Imaging Centre in 2022. There was also a change of Designated Individual (DI) in August 2019.

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 inspection:

Standards assessed against during inspection

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

Review of governance documentation

The establishment's self-assessment documentation, provided by the DI and Research Governance, Ethics and Integrity Officer in advance of the inspection, was reviewed. Policies and procedural documents relating to all licensed activities, including overarching standard operating procedures and risk assessments were also assessed. Documents detailing staff training, audits and incidents were reviewed, as well as consent-seeking procedures and information used to support the seeking of consent from donors.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Audit of records

The assessment included audits of two research tissue banks and four other research collections. The establishments internal audits were also reviewed which focussed on consent, traceability, sample storage, use and disposal, documentation, and training.

Meetings with establishment staff

The assessment included discussions with individual researchers and project leads, the Research Governance, Ethics and Integrity Officer for human tissue and the DI.

Report sent to DI for factual accuracy: 05 July 2022

Report returned from DI: 7 July 2022

Final report issued: 12 July 2022

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: 27 September 2022

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.