Inspection report on compliance with HTA licensing standards
Inspection date: **29 April 2024**

UK Biocentre
HTA licensing number 12624

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
UK Biocentre, hub site (MK7 8AT)	Licensed	Not licensed
UK Biocentre, Satellite site (OX2 0ES)	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.

The UK Biocentre (‘the establishment’) was found to have met all of the HTA’s standards.

Advice

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

Number	Standard	Advice
1.	C1(c)	The DI carries out a robust review of template consent forms provided by clients, to ensure that they meet the requirements of the Human Tissue Act 2004 (HT Act 2004). This review is carried out whilst a contract is set up between the establishment and the client. The current wording in the agreement states that the client is required to provide a copy of the consent form prior to the initiation of any research, however, does not clearly define that appropriate and valid consent is in place and the responsibility for ensuring such consent rests with the client. The DI should consider revising the wording in the template agreement so that it states that it is the client’s responsibility to ensure that only material with associated consent will be transferred to the establishment for storage, processing and use (as appropriate).
2.	PFE2(c)	The DI should consider adopting regular trend analysis of critical storage temperatures. This may help with preventative maintenance of equipment and help in the detection of malfunctioning equipment.

Background

The UK Biocentre (the establishment) is a sample management and bioprocessing facility with automated critical storage units. It operates under a hub-satellite licensing arrangement, with processing and storage activities taking place at the hub site and storage only taking place at the satellite site.

The establishment provides a tailored advice service around study management and undertakes processing of relevant material for the extraction of DNA or RNA. The establishment also provides a storage service, through contractual agreement, for the human tissue on behalf of other HTA-licensed establishments. Consent is not sought at the establishment.

This was the 2nd routine inspection of the establishment, with the previous inspection being undertaken in 2016.

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

Of the 47 HTA standards, 40 standards were assessed (standards published 3 April 2017). HTA standards, C1(b), (d),(e),(f) and C2(a),(b),(c) were not applicable as the establishment is not involved in seeking consent.

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to, standard operating procedures for licensable activities, key policies, a range of audits, meeting minutes, staff training records, sample tracking system, temperature monitoring data and incidents.

Visual inspection

There was no visual inspection of the premises; however, a pre-recorded virtual video tour of the premises showing areas of receipt, processing laboratories and storage areas was reviewed.

Audit of records

No traceability audit was carried out; however, the audit schedule and a range of audits undertaken by the establishment were reviewed as part of the assessment.

Meetings with establishment staff

A round table discussion was carried out with establishment staff which included the DI and Persons Designated (PD) under the licence.

Report sent to DI for factual accuracy: 22 May 2024

Report returned from DI: 24 May 2024

Final report issued: 24 June 2024

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.