Inspection report on compliance with HTA licensing standards
Inspection date: **19 October 2022**

OCDEM (Oxford Centre for Diabetes Endocrinology & Metabolism)
HTA licensing number 12326

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
OCDEM (Oxford Centre for Diabetes Endocrinology & Metabolism)	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 OCDEM (Oxford Centre for Diabetes Endocrinology & Metabolism) ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems and Traceability. These related to consent-seekers' training records, internal audits, registers of tissue slides and disposal records.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	There were no accessible records held by the DI to determine who is appropriately trained to seek consent. Staff hold their own records and self-certify that they have completed the relevant training.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities	Although the establishment confirmed that some audits have taken place, these were limited to stock-checks and not all audits were scheduled or documented.	**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.	There was a register of tissue blocks; however, the slides that are made from the blocks were not recorded in the registers of donated material.	**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.	There were disposal records for some of the collections.	**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)	The *'Staff Donor Consent SOP'* (CRU042) does not detail the training requirements for consent seekers. The DI is advised to detail the requirements to ensure that staff are fully aware that consent cannot be sought without expected training being completed. The DI may also wish to reference the HTA's Codes of Practice A (Consent) and E (Research).
2.	GQ1(a)	The *'Sample Logging, Storage and Tracking for the Purposes of Research'* SOP (SOP9) references the HTA's old Codes of Practice. Following substantial stakeholder engagement, revised Codes of Practice and licensing standards came into effect in 2017, and the DI is advised to make sure these references are updated.
3.	GQ1(a)	The establishment is in the process of adopting a new quality management system. The DI is advised to implement this system as soon as possible to aid with streamlining the governance processes.
4.	GQ1(b)	Some of the document version numbers which are displayed on the front covers and document footers do not match with the review history detailed within the document. The DI is advised to review the documents and correct any discrepancies between version numbers.
5.	GQ2(a)	To provide greater assurances on whether the establishment is meeting regulatory requirements, and those of their own systems, the DI is advised to widen the scope of activities that will be subject to auditing. In parallel

		with this, and for the same reasons, the DI is advised to schedule different types of audit; for example, vertical audits to cover full sample traceability.
6.	GQ2(b)	The DI was not aware of some of the audit findings relating to non-compliances. The DI is advised to have oversight of all the audit reports in order to identify issues and areas for improvement.
7.	GQ3(a)	Staff are required to complete online training relating to human tissue legislation prior to their involvement in licensed activities. 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.
8.	GQ5(a)	There is no specific incident reporting SOP but procedural detail is incorporated into the *'Liquid Nitrogen Failure'* SOP (SOP17). The DI is advised to develop and implement a standalone SOP, detailing how staff should use the incident reporting system, with more examples of what adverse events should be included.
9.	PFE2(d)	The *'Liquid Nitrogen Failure'* SOP (SOP17) details that two, manually-filled tanks are to be used in emergencies. The DI is advised to include details of the location of these tanks so staff know where to find them in the event that the contingency plan is initiated.

Background

OCDEM (Oxford Centre for Diabetes, Endocrinology & Metabolism) has been licensed by the HTA since September 2007. This was the third inspection of the establishment; the most recent previous inspection took place in October 2016.

Since the previous inspection, there has been some changes to the licence arrangements including a change in Designated Individual (DI) in September 2017 and a change of the Corporate Licence Holder contact in October 2018.

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

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

Review of governance documentation

Policies and procedural documents relating to all licensed activities, including standard operating procedures and risk assessments, were assessed. Documents detailing staff training 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

Records of internal audits were reviewed including stock-check audits of samples and locations. The inspection team also reviewed the establishment's four separate databases that log samples from receipt to use or disposal.

Meetings with establishment staff

The assessment included discussions with the Head of OCDEM, who holds the position of DI, the IT Manager, the Biobank Manager and the Laboratory Manager and Safety Officer.

Report sent to DI for factual accuracy: 18 November 2022

Report returned from DI: 24 November 2022

Final report issued: 28 November 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.