Virtual Regulatory Assessment (VRA) report on compliance with HTA licensing standards
Assessment date: **25 May 2021**

University College London (UCL) Eastman Dental Institute
HTA licensing number 12277

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 UCL Eastman Dental Institute (EDI), Rockefeller Building	Licensed	Not licensed
Satellite UCL EDI, Royal Free Hospital	Licensed	Not licensed
Satellite UCL EDI Continuing Professional Development	Licensed*	Not licensed

* = Establishment is licensed to carry out this activity but is not currently carrying it out.

Summary of assessment 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 Eastman Dental Institute (the establishment) had met the majority of the HTA's standards, one minor shortfall was found against GQ2(a) for Governance and quality systems. This was in relation to the absence of a documented audit schedule and corrective action was put in place before the end of the assessment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

Minor Shortfalls

Standard	Assessment findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	Although annual audits of traceability were being performed, there was no documented schedule of audits covering all relevant licensable activities. *Prior to the end of the assessment, the DI submitted evidence of the action taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**

Advice

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

Number	Standard	Advice
1.	C2(c)	Research activities have not taken place since March 2020, due to the COVID-19 pandemic. The DI is advised to consider the needs for consent refresher training before research and consent-seeking recommence.
2.	PFE2(c)	At the new satellite site, the temperature-monitored -80ºC freezers will have an external alarm and call-out system installed. The DI is advised to implement regular challenging of the temperature alarm callout system and the audible temperature alarms to ensure that they function as expected.
3.	N/A	The DI is advised to put in place Persons Designated (PDs) at the hub site to support her oversight of the biobank, including when the DI may be temporarily absent.

Background

Eastman Dental Institute is an academic establishment that houses the UCL Eastman Biobank. Relevant material is stored for the purpose of conducting research in connection with disorders or functioning of the human body, including genetic analysis. Storage is for specific research projects and storage for future use (unspecified research) as part of the biobank. Research groups within UCL can access the stored samples after approval from the Eastman Biobank Access Committee. Relevant material currently stored at the new Royal Free Hospital satellite site for specific research projects does not require critical storage conditions. Samples currently stored at this site in critical storage conditions (-80ºC freezers) are held under approval from a recognised Research Ethics Committee.

Eastman Dental Institute has been licensed by the HTA since August 2007. This was the first VRA of the establishment. Since the previous inspection in 2011, there have been changes to key people working under the licence including the Designated Individual in 2017 and the Corporate Licence Holder contact in 2018. No licensable activities are taking place at the EDI Continuing Professional development satellite site.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The assessment covered the following areas:

Standards assessed against during inspection
Standards T1(f) and PFE2(b) were not applicable to the current activities undertaken by the establishment. All remaining 45 licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The assessor undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to all licensed activities, consent documentation, standard operating procedures and traceability systems. Documents detailing staff training, adverse events, incidents, governance meetings, risk assessments and audits were also reviewed.

Visual inspection
There was no site visit inspection associated with the assessment.

Meetings with establishment staff
The assessment included discussions with the Professor of Endodontology, who holds the position of DI, the PD at the satellite site and a consent seeker.

Report sent to DI for factual accuracy: 17 June 2021

Report returned from DI: 18 June 2021

Final report issued: 29 June 2021

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.