Inspection report on compliance with HTA licensing standards
Inspection date: **29 March 2023**

# UCL Cancer Institute

HTA licensing number 12055

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 site**<br>UCL Cancer Institute | Licensed | Not licensed |
| **Satellite site**<br>Charles Bell House | Licensed | Not licensed |
| **Satellite site**<br>Royal National Orthopaedic Hospital and UCL Institute of Orthopaedics | 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 UCL Cancer Institute ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems, and Premises, facilities and equipment. The shortfalls related to standard operating procedures (SOPs), investigation of adverse events, cleaning and decontamination procedures, and monitoring of freezer temperatures.

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*

| **GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process** | | |
|---|---|---|
| a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. | SOPs have been developed by staff at the Research Tissue Bank (RTB) and are used by all groups working under the licence, after being modified by each group. While there was variation within groups the SOPs did not provide sufficient detail for all licensable activities. For example, SOPs did not provide:<br>• details for the periodic testing of the freezer alarms<br>• details for how to respond to alarms out of hours<br>• instructions for how to use the remote monitoring system<br>In addition, there was no documented process in place to ensure that relevant material held under project specific recognised Research Ethics Committee (rREC) approval was transferred to the governance of the HTA licence when the approval expired, or to notify the LH of relevant material held on the licensed premises outside of the DI's oversight. | **Minor** |

| GQ5 There are systems to ensure that all adverse events are investigated promptly | | |
|---|---|---|
| b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made. | A review of incidents at Charles Bell House identified several occasions where a small number of samples were lost. On one occasion this was attributed to a fridge failure while the responsible investigator was absent, but no preventative measures appear to have been identified that could be enacted to limit the possibility of a recurrence.<br><br>Another incident, investigated in 2023, identified the loss of 1 slide in 2017, multiple slides in 2018, 1 slide in 2019, and multiple slides between March 2021 and December 2021. The investigation concluded that some slides may be recorded as lost due to inaccurate data transcription when moving to an online sample database in 2021; others may have been lost - together with other items - when the laboratory space was repurposed to support the national COVID-19 testing response in 2020. However, no corrective or preventative actions have been identified or enacted. | **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 refrigerators and freezers. | **Minor** |

| PFE2 There are appropriate facilities for the storage of bodies and human tissue | | |
|---|---|---|
| c) Storage conditions are monitored, recorded and acted on when required. | During the inspection of the storage areas at Charles Bell House, it was found that one of the in use -80°C freezers had its local audible alarm muted over 2 weeks previously, with the visual alarm continuing to flash. In addition, it was confirmed that the remote alarm units for all -80°C freezer units within that area were unable to send an alarm signal due to Information Technology (IT) issues. As a result, it was only possible for staff to respond to local audible/visual alarms, which were not available on the muted unit. | **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) | The freezer temperature ranges used by different groups working under the licence varied. The DI is advised to review the temperatures defined in establishment SOPs to ensure they meet expectations and individual group requirements. |

| | | |
|---|---|---|
| 2. | GQ1(a) | Material Transfer Agreements (MTAs) with three external groups were reviewed. One MTA referred to the old HTA Code of Practice 5 on Disposal. The DI is advised to review MTAs and other documents to ensure that references are current. |
| 3. | T1(c) | The DI does not currently have oversight of sample records held by the different groups working under the licence. The DI is advised to consider implementing a system that allows him to have ready access to the records of the samples held by the different research groups. This will ensure that the DI is able to gather an accurate record of all material held under the licence at any point in time. |
| 4. | T1(c) | Several research groups working on the licensed premises routinely work with material held under project specific rREC approval. To improve awareness and oversight of storage requirements for all material held on the licensed premises, the DI is advised to implement a system to record and track the expiry dates of REC approvals. This will allow the DI to be aware of any material coming to the end of its approval so that it can be transferred to the governance of the HTA licence, transferred elsewhere, or disposed of. |
| 5. | PFE2(c) | The DI is advised to define a temperature range for RT storage and to implement a monitoring system for areas with RT storage. This will help to provide assurance that blocks and slides are maintained in suitable storage conditions. |
| 6. | PFE2(c) | The DI is advised to consider developing standardised signage for all storage units used by groups working under the licence. This will provide assurance that all information on storage units is provided consistently and enables a shared understanding of expectations. |
| 7. | PFE2(c) | The DI is advised to formally implement a system where the temperature plots from the freezer and LN2 monitoring systems are regularly reviewed as this may indicate a potential failure of the units before it occurs. |

## Background

UCL Cancer Institute is part of University College London (UCL) and stores a range of tissues and bodily fluids for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'. Functioning as a Research Tissue Bank (RTB) with recognised Research Ethics Committee approval, relevant material is released to groups within, and external to, UCL after an application has been made to the Biobank Ethical Review Committee (B-ERC).

UCL Cancer Institue has been licensed by the HTA since April 2013. This was the second inspection of the establishment; the most recent previous inspection took place in August 2014.

Since the previous inspection, the establishment has added three satellite sites to the licence, and revoked four. In addition, the establishment has appointed a new LH contact (LHc) and three new Persons Designated (PDs).

## 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*

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not store material from the deceased (standards published 3 April 2017).

*Review of governance documentation*

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, agreements with suppliers, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking spreadsheets and databases used to record and track relevant material, audits, and incidents.

*Visual inspection*

The site visit included a visual inspection of areas where samples were stored, at the hub site and the satellite site at Charles Bell House. There was no physical inspection, or review of stored samples, at the Royal National Orthopaedic Hospital and UCL Institute of Orthopaedics satellite site during this inspection. The visual inspection at the hub site included a review of the areas where RTB material is stored in -80°C freezers, at room temperature (RT), and in Liquid Nitrogen tanks (LN2). In addition, five other laboratories storing relevant material released from the RTB, and using standarised procedures provided by the RTB, were also inspected. At Charles Bell House storage areas utilised by two groups working under the licence were assessed, and included both -80°C and RT storage.

*Audit of records*

During the visual inspection, records for 21 samples in storage were reviewed. These samples comprised samples in -80°C freezers (sample to record), stored at RT (sample to record), and in LN2 storage (records only). In all cases, confirmation of consent was confirmed. While minor discrepancies were identified there was no loss of traceability. During the sample audit, several samples were identified that were held under recognised Research Ethics Approval (rREC) or under approvals from another RTB, including two collections of RT tissue where the rREC approval had expired, but the tissue had not been added to the licensed establishment's traceability system (see shortfall against GQ1(a)). Subsequent to the inspection, the DI was able to provide sufficient information to confirm that there had been no loss of traceability for the samples, and to provide an assurance that appropriate consent was in place for the material.

In addition, six internal audits of research groups against the HTA's standards were reviewed (three from January 2020 and three from February 2023). A further five research group self assessments from 2023, comprising sample tracking audits - covering storage location, confirmation of consent and database entries - were also reviewed. Three incidents reported in 2023 were also reviewed, two of which were still open and under investigation, and one of which was complete.

In addition to the documents above, three Material Transfer Agreements (MTAs) with external groups were reviewed.

*Meetings with establishment staff*

The inspection included disscusions with the DI, PDs and other staff working under the licence. This included the biobank manager and representatives of the different research groups working under the licence at the hub site and Charles Bell House satellite site.

**Report sent to DI for factual accuracy: 2 May 2023**

**Report returned from DI: No factual accuracy or request for redaction comments were made by the DI**

**Final report issued: 24 May 2023**

**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: 3 August 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.