Inspection report on compliance with HTA licensing standards
Inspection date: **24, 27 and 28 April 2023**

Charing Cross Hospital

HTA licensing number 12275

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 Charing Cross Hospital	Licensed	Not licensed
Satellite site Northwick Park and St Mark's Hospital	Licensed	Not licensed
Satellite site Chelsea and Westminster Hospital	Licensed	Not licensed

Satellite site Imperial College London (South Kensington)	Licensed	Not licensed
Satellite site Imperial College London (White City)	Licensed	Not licensed
Satellite site Hammersmith Hospital	Licensed	Not licensed
Satellite site St Mary's Hospital	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.

Charing Cross Hospital ('the establishment') was found to have met most of the HTA's standards; however, five minor shortfalls were identified against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to consent documentation, risk assessments, traceability, disposal and storage capacity.

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 assessment.

Compliance with HTA standards

Standard	Inspection findings	Shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice		
C1(a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice	One consent form had not been signed or properly completed by the research participant, meaning that the expected evidential trail was incomplete. The donated sample had been subsequently stored and used for research. Other consent forms had not been completed consistently; for example, missing patient signature or no information on who had sought consent for research. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	Shortfall
GQ6 Risk assessments of the establishment's practices and processes are regularly, recorded and monitored		
GQ6(a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	There were no documented risk assessments to provide assurance that this standard was met. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	Shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
T1(c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	A variety of sample traceability approaches were in use across the different research groups. Some research groups did not have robust processes to enable samples to be traced back to consent For example, one group was using a laboratory identification number which is comprised of a two digit number and the initials of the researcher which links through to the patient and the consent form. During an audit trail, this laboratory identification number was shown to link to three different patients which made it difficult to establish the correct patient and their consent form. Another group was using paper notelets with an adhesive strip, which may be misplaced or lost. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	Shortfall
T2 Bodies and human tissue are disposed of in an appropriate manner		
T2(b) The date, reason for disposal and the method used are documented.	The standard operating procedure (SOP), 'Process for disposing of human tissue' did not ensure that the date, reason and method for disposal were documented. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Standard	Inspection findings	Shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
PFE2(a) There is sufficient storage capacity	There was insufficient storage capacity at the South Kensington site where cadaveric parts are stored. This had resulted from a delay in disposal of material but there was no evidence that any action had been taken to manage the capacity issue. *"The establishment submitted sufficient evidence to address this shortfall before the report was finalised."*	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	The DI should consider implementing a check of completed consent forms to ensure that forms meet expected requirements and any non-conformances can be identified and rectified.
2.	GQ1(a)	Although SOPs are reviewed annually, the change control table at the end of each SOP is completed only if there has been a material change. To improve document control, the DI is advised to consider recording the annual review of the SOPs regardless of whether the SOP has changed or not.
3.	GQ2(a)	The establishment has in place a robust approach to carrying out audits of all research groups. The DI should consider reviewing the level of detail captured in the audit form so that if this information is review retrospectively, it demonstrates why a particular area was deemed to have been met. The DI should consider reviewing the level of evidence that is recorded to provide assurances that a particular area was deemed to have been met.
4.	PFE2(c)	The DI is advised that each group should review temperature trends on a regular basis. This may help to identify freezer problems before a failure occurs.
5.	PFE2(c)	The DI should consider regular testing of freezer alarms to ensure that the alarm system is working as expected.

Background

The establishment operates under a hub-satellite licensing arrangement, with Charing Cross as the hub site and six satellite sites. The Imperial College Healthcare Tissue Bank is hosted by the establishment and enables researchers to collect, store and use human tissue for research purposes. Material can be accessed and used for research by researchers with approval from the tissue bank. Furthermore, tissue collections that have been previously stored under the governance of an NHS research ethics approval can also registered under the tissue bank ethical approval and subsequently accessed with approval from the tissue bank steering committee for use in research.

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 standards were assessed (standards published 3 April 2017).

Review of governance documentation

A number of documents were reviewed during the assessment, which included but were not limited to: SOPs for licensable activities, key policies, traceability audits, staff competency records and records relating to traceability.

Visual inspection

A visual inspection and tissue traceability audit was undertaken at the hub and six satellite sites.

Audit of records

The following traceability audits were carried out at the hub and satellite sites.

Hub – Charing Cross Hospital

Three tissue blocks were identified from the pathology archive and traced to their respective records, including consent evidence. No discrepancies were noted.

A file note for a block was selected which stated that a block had been issued to a project. No discrepancies were identified.

During the visual inspection, an audit of three samples was carried out. One sample was identified from storage location to record and two samples were identified from records to storage locations. No discrepancies were identified and there was confirmation of consent for all three samples.

Satellite - Chelsea and Westminster Hospital

Three records of human tissue were identified and traced through to their respective storage locations for the reproductive immunology research group. No discrepancies were identified; however, it was difficult to establish how the traceability records linked with the consent forms, as all consent forms are recorded with the same laboratory identification number and not a unique reference number (please refer to the related minor shortfall).

An audit of three tissue samples was undertaken from storage locations to records - no discrepancies were identified.

Furthermore, a tissue traceability audit was carried out for two stored samples. The consent forms were not accessible at the time of the inspection; however, no discrepancies were identified in relation to the tissue traceability audit carried out.

Satellite site- South Kensington

An audit was carried out from traceability records to storage of four orthopaedic specimens. The material transfer agreement (MTA) associated with these bones was reviewed to confirm consent requirements were met No discrepancies were identified.

Satellite site - St Mary's Hospital

An audit was carried out from consent form to storage location. It was identified during the review of the associated consent form that the patient had not completed the research section of the consent form (please refer to the related minor shortfall). The sample was identified as being in the correct location.

On review of other consent forms, it was noted that some had not been completed consistently; for example, missing patient signature or no information on who had sought consent for research (please refer to the related minor shortfall).

Satellite site - St Mark's Hospital

During the review of the consent forms for two of the 'sub-collections', it was noted that some of the consent forms had not been completed fully, with gaps in sections relevant to research.

An audit was carried out of six samples, of which five were audited from records to storage locations and one from storage location to records. No discrepancies were identified.

Satellite site - Imperial College - White City

An audit was carried out from traceability records to storage locations for four frozen blocks. The MTA associated with this specimen was also reviewed to confirm consent requirements were met.There was a typographical error in the recording of the numbering of the blocks; however, the traceability system indicated these were the correct donor samples. There were 30 slides associated with this donor and on inspection of the storage locations it was noted that only 29 slides could be accounted for. It was established that this slide was on a separate spreadsheet. No other discrepancies were identified.

Satellite site - Hammersmith Hospital

Audit trails were followed from the storage locations of two larger specimens. A review of the MTA associated with the specimens was also reviewed. There were no discrepancies found.

Audit trails were also followed for a second ‘sub-collection’ - audits of two samples were carried out from records to storage locations. No discrepancies were identified.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and Persons Designated across the satellite sites.

Report sent to DI for factual accuracy: 25 May 2023

Report returned from DI: 12 June 2023 (no comments)

Final report issued: 30 June 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.