Inspection report on compliance with HTA licensing standards
Inspection date: **27 October 2022**

King's College London

HTA licensing number 12521

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
King's College London (Guy's campus)	Licensed	Not licensed
Franklin-Wilkins Building	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.

King's College London ('the establishment') was found to have the met most of HTA's standards; however, two minor shortfalls were identified against standards for Consent (C1) in relation to material from the deceased and Governance and Quality Systems in relation to audits (GQ2).

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(c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.	The establishment could not provide full assurance that appropriate consent had been obtained for the pancreatic islet tissue from deceased donors that it receives for storage and use in research from another establishment. This is because the Material Transfer Agreement (MTA) states that the consent is obtained from the donor's 'next of kin'. There is a risk that this terminology and approach may not line up with the requirements of the HT Act.	**Minor**

Standard	Inspection findings	Shortfall
GQ2 There is a documented system of audit		
GQ2(a) There is a documented schedule of audits covering licensable activities	Audit activities have not resumed since they were paused during the pandemic and there was no documented audit schedule for any of the groups. It was of particular concern that there have been no audits of the 'TIN-TIN Biobank', which is an HRA-approved research tissue bank (RTB) established in 2019.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(a)	Although consent forms were checked during the previous annual audits, the DI may wish to consider adopting an approach where Research Nurses or other staff check the completeness of consent forms at the time the consent forms are completed. This will help to ensure that any issues with the completion of the consent forms can be rectified earlier.
2.	GQ1(a)	The establishment has in place overarching Standard Operating Procedures (SOPs) for all activities. These have been locally adapted for some of the RTBs. It was noted during the document review that some SOPs do not state that the method of disposal should be recorded. This information is contained in the core overarching SOP for Disposal developed by the Designated Individual. To reduce the risk of individual groups missing key information in the overarching SOPs, the DI may wish to consider highlighting steps that must be included in locally adapted procedures to reduce the risk that this information and other key details are overlooked.
3.	GQ1(a)	The 'TIN-TIN Biobank' group's SOP for serious adverse events (SAEs) makes reference to the definition for SAEs and Serious Adverse Reactions (SARs) under The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). This is not relevant to the research sector and should be removed from the SOP.
4.	GQ1(b)	The DI should consider adopting a uniform approach to document review cycles as these are not consistent between RTBs. The majority of review cycles are two to three years but can be as long as eight years. Ensuring that all SOPs are reviewed using a consistent and reasonable review cycle should reduce the risk of practices becoming outdated.

6.	GQ6(a)	At present some of the RTBs are operating at 75% storage capacity. The DI is currently developing a strategy for storage capacity and is carrying out a piece of work to establish storage and capacity needs for each group. As part of this work, the DI may wish to consider carrying out an assessment of risks based on the current capacity and whether there is a need to make additions to the University's risk register.
7.	PFE2(c)	The DI is advised to document testing of critical storage temperatures that is done to ensure that the alarm system and notification procedures function as expected.
8.	PFE2(d)	Although each area has a respective contingency plan in place, with on-site contingency available, the DI may wish to consider the need for off-site storage in the event of a catastrophic failure on site.

Background

The establishment is a university that stores relevant material under the governance of RTBs in the areas of infectious diseases, dermatology, endocrinology, dentistry and transplant immunology. Across the hub and the satellite, there are 18 different research groups which store material either under the governance of ethically-approved research or the HTA licence.

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, 46 were assessed (standards published 3 April 2017). Standards PFE2(b) was not applicable.

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

There was no site visit; however, a meeting with relevant staff members took place to discuss the PFE standards.

Audit of records

No traceability audits were carried out; however, previous audit records around traceability were reviewed as part of the inspection. It was noted that there were no documented audits for the 'TIN-TIN Biobank'. The focus of the inspection was primarily on the RTBs and did not include all research groups storing material under the licence.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and PDs (Persons Designated).

Report sent to DI for factual accuracy: 24 November 2022

Report returned from DI: 2 December 2022 (no comments)

Final report issued: 9 December 2022

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: 26 May 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.