Inspection report on compliance with HTA licensing standards
Inspection date: **03 December 2025**

The Francis Crick Institute Laboratory

HTA licensing number 12650

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
The Francis Crick Institute Laboratory	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.

The Francis Crick Institute Laboratory ('the establishment') was found to have met all HTA standards.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C1(a)	There was good documentation of consent procedures, along with the information used to support consent-seeking. However, for one of the collaborative studies, the consent form had a reference to the superceded version of the Patient Information Sheet (PIS). The DI is advised to ensure that consent evidence contains correct references to the documentation that was used to support consent-seeking.

Background

The Francis Crick Institute is a London-based biomedical research facility funded by the Medical Research Council (MRC), Cancer Research UK, Wellcome, University College London, Imperial College, and King's College London. The organisation has a huge collection of relevant material from various sources both locally and from abroad. They also obtain material from their Healthy Volunteer (HV) programme. The establishment has a Research Tissue Bank (RTB) for rare dermatology diseases.

The Francis Crick Institute Laboratory has been licensed by the HTA since 25 August 2016. This was the third inspection of the establishment; the most recent inspection was a routine site visit that took place in March 2019. Since the previous inspection, the establishment has appointed a new DI, a Corporate Licence Holder contact (CLHc), and several Persons Designated (PDs).

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

46 of 47 HTA licensing standards were covered during the licence assessment (standards published 3 April 2017). PFE2(b) was not relevant as the establishment does not store deceased donors.

Review of governance documentation
A number of documents were reviewed during the assessment which included policies and Standard Operating Procedures (SOPs) relating to licensed activities, consent forms and donor information sheets, material transfer agreements (MTAs), audit reports, risk assessments, meeting minutes, reported incidents, temperature monitoring for the storage units, records of servicing, and staff training records.

Visual inspection
No visual inspection was undertaken as part of this inspection. However, a meeting took place with relevant staff members to discuss compliance with the Premises, facilities and equipment (PFE) standards. Digital images of fridges, freezers, including the establishment's Freezer Farm, and Liquid Nitrogen storage facilities, were viewed remotely.

Audit of records
No traceability audit was carried out. However, a review of recent audits conducted for several research groups was undertaken as part of the assessment.

Meetings with establishment staff
Roundtable discussions were carried out with establishment staff which included the DI, Human Tissue Governance Manager, Research Governance Officer, Contracts Coordinator, Research Portfolio Manager, HV Programme staff, Standards and Quality Lead, and members of the wider technical team.

Report sent to DI for factual accuracy: 11 December 2025

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

Final report issued: 12 December 2025

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.