Inspection report on compliance with HTA licensing standards
Inspection date: **17 July 2025**

Royal Papworth Hospital
HTA licensing number 12212

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 Cambridge Biomedical Campus, CB2 0AY	Licensed	Not Licensed
Satellite site The Victor Phillip Dahdaleh Heart & Lung Research Institute, CB2 0BB	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 Royal Papworth Hospital ('the establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems and Traceability. These shortfalls related to the alignment of practice with documented policy and procedures, and the assignment of unique codes to each of the products associated with a donation.

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.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	At the time of the assessment, not all practices within the Mesobank research tissue bank aligned with the documented policies and procedures. Examples included, but were not limited to, document control (DN001), sampling handling (SOP124) and consent (SOP103).	**Minor**

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
a) Identification system which assigns a unique code to each donation and to each of the products associated with it	At the time of the assessment, the Royal Papworth research tissue bank did not allocate a unique code to each of the products associated with a donation.	**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.	N/A	It was noted during the inspection that the satellite site currently undertakes more licensable activity than the hub. The DI is advised to contact the HTA licensing team to review and, if necessary, amend the hub and satellite designations on the establishment's licence to reflect the current operational arrangements.
2.	C1(a)	The documented procedure on consent did not address situations or events in which consent might need to be renewed. The DI should consider including reconsent in the documented procedure, SOP103.
3.	C1(c)	The Mesobank research tissue bank had documented agreements with third party suppliers of relevant material. The DI is advised to strengthen assurances regarding consent within future agreements.

4.	GQ4(a)	The governing NHS Trust had documented policies and procedures in place for the creation, review, amendment, retention, and destruction of records. However, these documents did not explicitly refer to the retention periods for sample-related records, such as completed consent forms and agreements. To enhance records management practices, the DI is advised to clarify how such records are managed within the framework of the Trust's overarching policy.
5.	GQ5(b)	The establishment had recently introduced a modified CAPA reporting and management procedure. The DI is advised to ensure that the implementation of the new system ensures that effective preventative as well as corrective actions are taken where necessary and that improvements in practice are made.

Background

The establishment stored material for local research projects and operated two tissue banks with approvals from a Health Research Authority Research Ethics Committee: Royal Papworth Hospital Research Tissue Bank (23/EE/0198) and Mesobank (23/EE/0139). The Royal Papworth Hospital Research Tissue Bank was established in 1997 and provided relevant material for cardiothoracic research. The Mesobank was founded in 2012 and was dedicated to mesothelioma research.

Royal Papworth Hospital has been licensed by the HTA since 2007. This was the second inspection of the establishment. Since the previous inspection in 2018, there has been one change in the Designated Individual (DI) and two changes to the named corporate licence holder. The hub premises were relocated in 2019, with the associated licence variation completed in 2022. Additionally, three satellite sites were added since 2018, although two were subsequently revoked. At the time of the inspection, the establishment held Mesobank samples on a permanent basis, whereas in 2018, it had only held such samples temporarily for processing and specialist analysis.

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

All 47 standards in the Research sector were assessed (standards published 3 April 2017).

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's licensed activities. These included policies and procedural documents relating to licensed activities, agreements with suppliers and recipients, risk assessments, meeting minutes, as well as staff training records, audits, consent templates and participant information sheets. In addition, staff demonstrated the systems in place for maintaining registers of donated material, as well as for recording sample receipt, release and disposal.

Visual inspection
No site visit was undertaken as part of this inspection. The establishment presented images of the storage facilities that allowed for the assessment of security measures and the signage on the individual storage units. The accompanying discussion also addressed key areas including storage capacity and monitoring, equipment maintenance, contingency planning, procedures for cleaning and decontamination, and personal protective equipment.

Audit of records
There were no sample audits carried out. A number of audits carried out by the establishment staff, which included audits covering processes and traceability of specimens, were reviewed.

Meetings with establishment staff
The inspection included discussions with the DI, PDs and other staff working under the licence.

Report sent to DI for factual accuracy: 31 July 2025

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

Final report issued: 18 August 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.