Inspection report on compliance with HTA licensing standards
Inspection dates: **03 December (remote) and 04 December (site visit) 2025**

Salford Royal Hospital

HTA licensing number 12291

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
Salford Royal Hospital, Stott Lane, Salford M6 8HD	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 the Salford Royal Hospital ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent and Traceability.

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

Standard	Inspection findings	Level of 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		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	During the inspection, a consent form had not been countersigned by the individual seeking consent in accordance with the documented consent procedure (SOP HTA09). *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained.	Although staff involved in the consent-seeking process were trained, their competency was not formally assessed.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	During a tissue traceability audit, it was noted that one sample tube was incorrectly labelled. Two further tubes were incompletely labelled, resulting in different sample types collected from the same donor on the same day sharing the same label code.	**Minor**
b) A register of donated material, and the associated products where relevant, is maintained	A tissue traceability audit identified that the freezer designations recorded in the electronic registers for two of the collections in storage were incorrect at the time of the inspection. *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.	GQ1(a)	At the time of the inspection, the establishment was developing a new system for staff to acknowledge they have read and understood key documents, including SOPs and risk assessments. The DI is advised to review the implementation of this process to ensure effective monitoring of staff compliance and engagement.
2.	GQ1(e)	The governing NHS Trust has an overarching complaints procedure. The DI is advised to document more clearly how complaints related to HTA-licensable activities are managed under this procedure.
3.	PFE3(a)	At the time of the inspection, temperatures in the two rooms housing freezers containing relevant material were maintained with portable air conditioning units. The DI is advised to closely monitor and consider undertaking a risk assessment of this arrangement - particularly with consideration to periods of warmer environmental conditions - to ensure freezer units continue to operate as expected, implementing preventative and/or corrective actions if required.

Background

Salford Royal Hospital has been licensed by the HTA since 2007. This was the 4th inspection of the establishment; the most recent previous inspection took place in February 2019. Since the last inspection, the names of the licensed premises, the Corporate Licence Holder, and the Corporate Licence Holder Named Contact have all changed. However, there have been no significant changes to the activities carried out under the licence. The establishment operates a research tissue bank with generic approval from a recognised research ethics committee and currently holds 14 biobank collections of relevant material under the licence. Relevant material for a small number of research projects is also stored under the 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 standards in the Research sector, 45 were assessed (standards published 3 April 2017). Standards C1(c) and PFE2(b) were not assessed, as the establishment did not store material from third parties or material removed from the deceased.

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities, including policies and procedures, sample release agreements, risk assessments, meeting minutes, staff training records, consent templates, and participant information sheets.

Visual inspection

The site was visited as part of the inspection. This included the access points and security arrangements as well as the room where relevant material was received prior to processing and the two rooms where material was stored. Staff also demonstrated several of the registers used to track the materials, with each collection recorded in a separate register.

A traceability audit of samples stored was undertaken, which included a review of the completed consent forms. Ten samples were selected from the registers for three collections and one research project and traced to their storage locations. All samples were located; however, one sample was in a different freezer than recorded in the register. Additionally, one sample tube was labelled incorrectly, and two others had incomplete labels (see minor shortfall identified against T1(a)). No discrepancies were identified in the corresponding consent forms.

An additional four samples were traced from their storage locations back to the register. For two of these samples, both from the same collection, the freezer designation recorded in the register was incorrect (see minor shortfall identified against T1(b)). In addition, one consent form had not been countersigned by the staff member seeking consent (see minor shortfall identified against C1(a)). No other consent or register discrepancies were found.

Audit of records

A number of audits carried out by the establishment staff, which included audits covering processes and traceability of specimens, were reviewed. Other records reviewed included those for the release of samples, disposal and cleaning, equipment servicing and temperature monitoring.

Meetings with establishment staff

The inspection included discussions with the DI, Persons Designated (PDs), and other staff working under the licence. These included facility and compliance managers as well as a consent-trained researcher practitioner.

Report sent to DI for factual accuracy: 29 December 2025

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

Final report issued: 12 January 2026

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.