

**The Christie**  
HTA licensing number 30004

Licensed under the Human Tissue Act 2004

**Licensed activities**

<b>Area</b>	<b>Storage of relevant material which has come from a human body for use for a scheduled purpose</b>	<b>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</b>
<b>Hub site</b> The Christie, 550 Wilmslow Road, Manchester, M20 4BX	Licensed	Not Licensed
<b>Satellite site</b> Manchester Cancer Research Centre, 555 Wilmslow Road, Manchester, M20 4GJ	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 Christie ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Consent.

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 inspection.

## Compliance with HTA standards

### Minor Shortfalls

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, the competency of some staff was not formally assessed.  <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i>	<b>Minor</b>

## Advice

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

Number	Standard	Advice
1.	C1(a)	The establishment has a documented procedure for the withdrawal of consent (T017, Withdrawal of Consent) and Material Transfer Agreement (MTA) templates for the release of material from the biobank. The DI is advised to incorporate specific requirements related to consent withdrawal within the MTAs to strengthen the effectiveness of the withdrawal process.
2.	C1(a)	Current practice is to check all completed consent forms for incoming biobank samples where consent was not sought by core biobank staff. To ensure that documented procedures accurately reflect current practice, the DI is advised to review and update the relevant policies and procedures to incorporate details of these and any similar checks.
3.	GQ1(a)	The establishment has policies and procedures in place at Trust, Divisional, and Directorate levels. The DI is advised to conduct a gap and consistency analysis across these documents to ensure they are appropriately cross-referenced, aligned, and as easy to navigate as possible. For example, HTA004 (Consent for the Removal, Use and Storage of Human Tissue in Research) and T001 (Obtaining and Recording Informed Consent) may benefit from restating, or expressly referencing, the provisions on re-consenting donors set out in section 6.5 of R&I 005 (Informed Consent in Research) to strengthen awareness and adherence to the documented procedures. See also Advice against GQ1(e) and GQ4(a).

4.	GQ1(e)	The Trust has an overarching complaints policy and procedure. The DI is advised to document how complaints related to HTA-licensable activities are managed under this procedure.
5.	GQ2(b)	The establishment has an established procedure for auditing samples (HTA008, Human Tissue Audit Procedures) and has piloted a new strategy for auditing evidence of consent linked to research collections. The DI is advised to monitor and review the new procedure to ensure that records of consent continue to be audited regularly and assessed for completeness, accuracy, and legibility.
6.	GQ4(a)	The Trust has an overarching records management policy and procedures. The DI is advised to document how records relating to HTA-licensable activities are managed within this framework.
7.	GQ5(b)	Adverse events under the licence are recorded and managed both locally and through the Trust-wide DATIX system. At present, the DI does not routinely have access to other potentially relevant DATIX reports. The DI is advised to engage with Trust colleagues to explore how their visibility of relevant incidents occurring elsewhere in the organisation can be improved, in order to support better integration, oversight, and forward planning.

## Background

The Christie has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2019. Since the last inspection, the Corporate Licence Holder contact has changed four times, a satellite site used as contingency premises after the 2017 fire has been revoked, and the hub premises have been extended. The establishment operates a research tissue bank (Manchester Cancer Research Centre Biobank) with generic approval from a recognised research ethics committee (22/NW/0237) and at the time of the inspection stored a further 31 research project collections 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, 46 were assessed (standards published 3 April 2017). Standard PFE2(b) was not assessed, as the establishment did not store 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, material transfer agreements, risk assessments, meeting minutes, staff training records, consent templates, and participant information sheets.

### *Visual inspection*

No site visit was undertaken as part of this inspection. The establishment presented images showing the access points, security measures, and storage facilities within both the hub and satellite sites. The accompanying discussion also covered key topics such as contingency storage arrangements, temperature monitoring, cleaning, equipment maintenance, and personal protective equipment.

### *Audit of records*

Consent forms, along with the storage locations and sample labels, were reviewed on-screen during the inspection for eight samples pre-selected by the Regulation Manager from four research collections. No discrepancies were identified. Fifteen audits carried out by the establishment staff over the previous three years were also reviewed. These included audits of the biobank and research collections, covering both procedural processes, records and sample traceability. Other records reviewed during the inspection included those for the release of samples, disposal, cleaning, equipment servicing and temperature monitoring as well as adverse events and transportation. Staff demonstrated the systems used to maintain sample registers and other records.

### *Meetings with establishment staff*

The inspection included discussions with the DI, PDs, and a biobank technician involved in seeking consent, as well as the Head of Quality & Governance and the Translational Research Project Manager.

### **Report sent to DI for factual accuracy: 11 March 2026**

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

**Final report issued: 27 March 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.