Inspection report on compliance with HTA licensing standards
Inspection date: **13 (Virtual Regulatory Assessment) and 14 &15 (site visit) November 2023**

John Radcliffe Hospital

HTA licensing number 12217

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
John Radcliffe Hospital, University of Oxford (Hub)	Licensed	Not licensed
Dorothy Crowfoot Building (Satellite)	Licensed	Not licensed
Peter Medawar building (satellite)	Licensed	Not licensed
Nuffield Orthopaedic Centre (satellite)	Licensed	Not licensed

The Churchill Hospital (satellite)	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 John Radcliffe Hospital ('the establishment') was found to have met majority of the HTA's standards; however, four minor shortfalls were identified against Consent and Governance and quality systems standards. These related to consent procedures, standard operating procedures (SOPs) on the release of tissue and records management.

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		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	Procedure GQ028, 'Seeking Consent for Brain and Spinal Cord Donation after the death of a donor', which is used by brain bank staff, did not include that consent must be sought from a suitable person in the hierarchy of qualifying relationships under the Human Tissue Act 2004 (HT Act).	**Minor**

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		
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose	The 'FRM021 OBB Consent form- Nominated Representative', which can be completed by a relative or nominated representative, refers to the term 'next of kin' (NOK) and did not reflect the requirements for consent to be obtained from a suitable person in the hierarchy of qualifying relationships under the HT Act. Supporting information did not include the relationships that would qualify to give consent, including the information sheet provided to the family.	**Minor**

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	The SOPs for the 'collated collections', which are tissue samples that have been adopted by an existing tissue collection held under licence, did not contain information about the process to be followed for release of tissue for use in project-specific, ethically approved research projects.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are provisions for back-up / recovery in the event of loss of records.	During the inspection, it was noted that one group did not have adequate back-up provision for disposal records - which were stored only in paper format - and a research group located within the Dorothy Crowfoot building did not have provisions in place for the recovery of paper consent forms in the event of their loss.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ2(a)	The establishment undertakes a range audits which focus on the HTA standards and traceability. The DI should consider also including audits which focus on processes. This will help to identify if processes are being followed and whether there are any specific training needs.

2.	GQ2(b)	The approach to documenting audits varies significantly, with some groups documenting comprehensive detail and others not. The DI should consider reviewing the current approach to documenting audits and consider developing guidance for staff on the expected level of detail. This should help to ensure that audit forms are completed consistently and provide sufficient detail.
3.	GQ5(a)	All incidents and adverse events, including those relating to human tissue, are reported on a governance system. It was noted that one of the collections had not reported an incident that should have been reported at the time. The DI is advised to ensure that all staff report incidents using the reporting systems in place to ensure that there is a clear oversight of the types of incidents arising across the collections.
4.	GQ6(a)	The establishment is in the process of adopting a new traceability system but only certain collections may adopt this system to manage the traceability of their specimens. The DI should consider carrying out an assessment of risks where particular collections opt out of using this new system, taking any appropriate actions to mitigate identified risks.
5.	GQ6(b)	For one collection, a risk assessment had been carried out for the transport and refurbishment of specimens, but a review date had not been identified and the document was not uploaded to the electronic quality management system. The DI is advised to ensure all relevant documents relating to risk assessments are accessible, managed and reviewed in line with expected governance arrangements.
6.	T1(c)	During a traceability check, for one collection, a specimen was not stored in the documented location. Although the specimen was immediately found, the DI should consider implementing inventory audits of collections to confirm record systems fully facilitate the complete traceability of relevant material.
7.	PFE1(a)	The floor covering in the Cryostore room in the Pharmacology building appeared cracked in places. The DI is advised to seek specialist professional advice on this matter, in case remedial action is recommended.
8.	PFE2(c)	The DI should consider adopting regular trend analysis of critical storage temperatures. This may help with preventative maintenance of equipment and detect any malfunctioning equipment ahead of a possible failure.

Background

This report describes the fourth site visit inspection of the establishment with the most recent inspection taking place in 2019. The establishment operates a large number of tissue collections, including research tissue banks, collated collections and single collections of human tissue. All collections have appropriate oversight and there is a registration/adoption process for all tissue collected under the research ethics approval to be stored under the governance of the HTA licence. The inspection involved a review of activities relating to the following collections:

- Pharmacology collection;
- Peter Medawar collection;
- Dorothy Crowfoot collection;
- Quantum Biobank;
- Oxford Musculoskeletal bank;
- Oxford Brain Bank;
- Oxford Radcliffe Biobank;
- QUOD biobank;
- Pathology Museum.

One collection was not reviewed due to time constraints.

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

46 of the 47 HTA standards were assessed (standards published 3 April 2017). PFE2(b) is not applicable as there is no storage of the deceased taking place.

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

A visual inspection and tissue traceability audit was undertaken at the hub and four satellite sites.

Audit of records

The following audits were carried out during the inspection.

Pharmacology collection

An audit of two samples, from storage locations to traceability records and the corresponding consent records, was undertaken. There were no discrepancies identified.

Paper records pertaining to disposal of blood samples were seen *(Minor shortfall, GQ4(a)).*

Peter Medawar collection

An audit of three samples, from storage locations to traceability records and the corresponding consent records, was undertaken. For one out of three of the samples, it was noted that the cap had a different identification number to that on the vial itself; this was noted as a minor discrepancy. The research group confirmed that this would be queried with the supplier.

Dorothy Crowfoot collection

An audit of eight samples from across the research groups based in the Dorothy Crowfoot building was undertaken, from traceability records and the corresponding consent forms to storage location. A further audit of two samples, from storage locations to traceability records and the corresponding consent records, was also carried out. There were no discrepancies identified.

Quantum Biobank

An audit of three samples, from storage locations to traceability records and the corresponding consent records, was undertaken. There were no discrepancies noted.

A further audit of one sample, from traceability record and consent record to storage location, was undertaken. There were no discrepancies noted.

Oxford Musculoskeletal bank

An audit of one sample, from traceability record and the corresponding consent form to storage location, and an audit of two samples, from storage locations to traceability records and the corresponding consent records, was undertaken. There were no discrepancies identified.

Oxford Brain Bank

Four records relating to brain donation were reviewed, including consent forms and traceability records to specimens in storage. This included a whole brain and a coroner's case. There were no discrepancies noted.

Oxford Radcliffe Biobank

An audit of two samples, from traceability records and corresponding consent records to storage location was undertaken. An audit of one sample, from storage location to traceability records and the corresponding consent record, was undertaken. No discrepancies were noted.

QUOD biobank

An audit of six samples, three from traceability records to storage locations and three from storage locations to traceability records, was undertaken. No discrepancies were identified.

Pathology Museum

An audit of two samples, from storage locations to traceability records, was undertaken and no discrepancies were identified. An additional audit of one sample, from traceability records to storage location, was also completed. The sample was not stored in the location specified but was immediately found.

Meetings with establishment staff

A roundtable discussion was carried out with establishment staff, which included the DI and Persons Designated across the satellite sites. This focussed on consent discussions and tissue banking for each of the collections.

Report sent to DI for factual accuracy: 13 December 2023

Report returned from DI: 10 January 2024 (with comments)

Final report issued: 10 January 2024

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.