Inspection report on compliance with HTA licensing standards
Inspection date: 26 June 2024

UKHSA Porton

HTA licensing number 12646

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
UKHSA Porton	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 UKHSA Porton ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Governance and quality systems and Traceability. The shortfalls related to risk assessments, sample inventory records, and traceability of samples during storage.

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
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The establishment's risk assessments did not cover all risks associated with licensed activities. For example they did not include an assessment of the risks associated with: • Samples being stored after withdrawal of consent, or beyond any limitations (such as a maximum time in storage) that may have been stipulated in the donor consent. • Long term storage of samples for DNA extraction being stored in the processing laboratory without being recorded in the sample tracking database or electronic inventory system. • Use of a shared -80°C freezer for cell cryopreservation that belongs to, and is in use by, a group whose staff have not had specific training for working with relevant material.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
b) A register of donated material, and the associated products where relevant, is maintained.	The establishment prepares and stores a DBS sample (on a collection card) for every sample deposited and processed at the establishment. These samples are not recorded in the establishment sample tracking database or sample inventory system.	**Minor**
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	Although staff were aware of the location for all samples being held onsite, the current procedures do not ensure that there is an audit trail that includes all sample storage locations. For example: • On receipt, samples for DNA extraction are stored in a -20°C freezer in the processing lab. While the expectation is that samples are processed within approximately two weeks, at the time of inspection samples had been stored in the freezer for several months. Whilst the electronic software system logs the number of blood tubes received for cell isolation, the presence of the blood tube for DNA extraction was only recorded on the paper depositor form. • After processing, isolated peripheral blood cells are cryopreserved at -80°C using a commercially available cell freezing block. Cryopreserved cells are then transferred to temporary storage in vapour phase Liquid Nitrogen (LN2) storage, before being collected by a dedicated team for long term storage. After collection, the samples may be stored temporarily in LN2 before being transferred to their final location, which is recorded in the establishment's electronic system. Transfer in and out of the -80°C freezer and the two interim LN2 storage locations is not recorded in the	**Minor**

	establishment systems. • In addition, during the sample audit it was noted that an LN2 storage tank had been thawed due to mechanical issues, and samples transferred to a contingency storage tank. While a Temporary Transfer Form had been completed and staff in the long term storage facility were aware of the temporary storage transfer, the electronic system had not been updated to reflect the new location of the samples.	

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.	GQ2(a)	The DI is advised to broaden the scope of internal audits to include procedural horizontal audits by staff involved in the processes as this may help to ensure that SOPs contain sufficient detail to accurately reflect current practices and to identify areas for improvement.
2.	GQ3(b)	Several areas containing human material are accesible to UKHSA staff who have not had specific training associated with the use of human material. The DI is advised to provide appropriate information and training to all staff who have access to human material so they are aware of applicable regulatory expectations.

3.	T1(c)	During the sample audit, it was noted that requests for release or destruction of samples were made by email. To strengthen traceability (audit trail), the DI is advised to consider how to best link requests for release or destruction to sample records.
4.	PFE2(a)	The DI is advised to label refrigerators, freezers and LN2 storage vessels containing human material so that staff are aware of the necessity to maintain the quality, safety, and security of such material and prevent mix-ups with other tissues.

Background

UKHSA Porton is part of the UK Health Security Agency. The establishment houses the European Collection of Authenticated Cell Cultures (ECACC) as part of the UKHSA Culture Collections at Porton Down. In addition, the establishment offers a contracted service for the separation of primary cells from blood samples and subsequent storage and onward derivation of cell lines (if required). Researchers depositing cells with the establishment take responsibility for donor consent.

UKHSA Porton has been licensed in the research sector by the HTA since March 2016. This was the first inspection of the establishment under the research sector standards. Prior to 2016 the establishment was licensed in the Human Application sector and, after licensing in January 2008, was subject to three site visit inspections. The most recent previous inspection was a themed inspection which took place in April 2013.

Since the establishment transferred to research sector licensing, it has appointed a new DI on three occasions, a new Licence Holder contact on three occasions, and changed its name.

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
There are 47 standards in the Research sector, of which 38 were assessed. Standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), C2(c), and PFE2(b) could not be assessed as the establishment does not directly seek consent, or store the deceased (standards published 3 April 2017).

Review of governance documentation
The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, agreements with depositors of relevant material, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the sample tracking database and the sample inventory system used to record and track relevant material, audits, and incidents.

Visual inspection
The site visit included a visual inspection of areas where samples are receipted into the establishment, processed, cryopreserved in a -80°C freezer, stored in vapour phase LN2 (the interim cryostore), and stored in vapour phase LN2 for long term storage (the main cryostore).

Audit of records
During the visual inspection records for seven samples were reviewed. These samples comprised a DBS card (see shortfall against T1(b)), a sample intended for DNA extraction stored at -20°C in the processing laboratory (see shortfall against T1(c)), samples currently stored in long term LN2 storage (see shortfall against T1(c)), a sample that had been returned to the depositor at their request, and samples that had been destroyed at the depositor's request (see *Advice*, item 1).

In addition, the two most recent internal audits were reviewed, as was an example Service Level Agreement with a sample depositor.

Meetings with establishment staff
The inspection included discussions with the DI, the Corporate Licence Holder contact, PDs and other staff working under the licence including staff involved with quality, operational, diagnostic, laboratory, and storage functions.

Report sent to DI for factual accuracy: 22 July 2024

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

Final report issued: 29 July 2024

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 17 December 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.