Site visit inspection report on compliance with HTA licensing standards

Leicester Royal Infirmary

HTA licensing number 12384

Licensed under the Human Tissue Act 2004 for the

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

04 to 06 June 2019

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH) and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Leicester Royal Infirmary had met many of the HTA's standards, three major and eleven minor shortfalls were identified against standards across all four of the HTA's standards groups.

Advice has been given relating to the Consent, Governance and quality system, and Premises, facilities and equipment standards.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual 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 Designated Individual 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 site visit 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.

Background to the establishment

Leicester Royal Infirmary (LRI) ('the establishment'), Glenfield Hospital and Leicester General Hospital, are all managed under the University Hospitals of Leicester NHS Trust (UHL). It is one of the biggest and busiest trusts in the country serving one million residents. The Robert Kilpatrick Clinical Sciences Building (RKCSB) at the LRI is the licence hub site, with both Glenfield Hospital and Leicester General Hospitals operating as satellites under the licence.

The University of Leicester (UoL) is an academic institution that has a current intake of around 17,000 undergraduate and post-graduate students. It has a research income of £55-60 million and is part of the "Midlands Innovation, a world-class research and innovation partnership, combining the collective excellence of universities in the Midlands to power growth across the region". UoL is the third satellite under the HTA licence.

The establishment has two Research Tissue Banks (RTBs): The University of Leicester Cancer Research Biobank and the Lung Health RTB at Glenfield. The establishment has been licensed by the HTA since November 2006. This was the establishment's third routine inspection; their previous inspections were carried out in May 2011 and September 2016. One minor shortfall was identified at the previous inspection, relating to the temperature monitoring of liquid nitrogen tanks.

Description of inspection activities undertaken

The inspection timetable was developed after consideration of the activities conducted under the licence, compliance update information and discussions with the DI. The inspection team reviewed the establishment's procedures for conducting activities under the licence. This involved interviews and group discussions with staff involved in consent seeking, quality management and sample management. The inspection also included a visual inspection of all areas where relevant material is stored under the licence. Audits of sample traceability were also conducted on randomly selected samples covering a range of storage areas:

- Nineteen tissue samples stored in -80°C freezers
- Five samples stored as wax blocks at room temperature (RT)
- Thirteen slides at room temperature (RT)
- Two samples in fixative at room temperature (RT)
- Four tissues samples stored in -20°C freezers

The majority of sample audits were recorded in various sample tracking systems. Some of these samples were found not to have unique identifiers. Consent forms were available for

some samples although for others there were no corresponding consent forms or consent form templates to determine their ongoing suitability to be stored under the HTA licence.

The establishment conducts numerous NHS Research Ethics Committee (REC) approved studies. There was a general (and incorrect) assumption amongst establishment staff that samples from REC-approved studies would automatically be stored under the HTA licence after REC approval had expired. Consent forms were not scrutinised to ensure these samples could be kept for further research after a study ends. There were some consent forms that evidenced that the samples had to be destroyed once the study has finished, or could be kept for an extended period of time and then used for genetic analysis only.

Inspection findings

The HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

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		
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.	There was an inconsistency in the availability of consent forms. There were samples that had been collected as part of a REC-approved study. This approval had now expired and copies of the consent forms were not available. It was not evident that these samples could continue to be stored for use for scheduled purposes under the HT Act. There were samples that had been acquired from an external RTB. It was not evident that these samples had consent for use for scheduled purposes under the HT Act. There was no documented evidence that checks had been made to ensure that commercially bought samples had been obtained with appropriate and valid consent	**Major**

c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.	There were tissue samples that had been acquired from a research collaborator in France. The Patient Information Sheet (PIS) and consent forms were available, however; these were in French and no English translation or other assurances had been sought.	**Minor**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	There is a lack of formal training for those staff seeking consent. Staff from several different research groups across the establishment, who have not had formal documented training, are taking consent from participants for studies.	**Major**
b) Records demonstrate up-to-date staff training.	There is an inconsistency and lack of documented consent training records for staff who work under the licence, across the entire establishment. It was evident that some staff had training records, while others had not. *Standard C2(c) could not be assessed*	**Minor**

Governance and Quality

Standard	**Inspection findings**	**Level of shortfall**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills		
b) There are documented induction programmes for new staff.	There are induction packs for new staff and training at each site. There is a lack of specific training and guidance for relevant new staff and students that addresses the requirements of the HT Act and the HTA's Codes of Practice.	**Minor**

Traceability

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) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.	Unique codes are not consistently applied to all samples held under the licence. The same unique code is often used for samples divided into multiple aliquots. This creates a lack of traceability for all samples from a donor and impairs the ability to ensure all samples can be identified if consent for continued storage and use is withdrawn.	**Minor**
b) A register of donated material, and the associated products where relevant, is maintained.	There are a number of registers for donated material at each site. During the traceability audit, there were a few samples there were not documented on the database.	**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.	The establishment conducts a large number of REC-approved studies and continues to store the associated samples for further research after the REC approval has expired. During the inspection, there were a number of times when staff were unsure if their samples were stored under the authority of a REC approval or the HTA licence.	**Minor**
T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	The date, reason for disposal and the method used are inconsistently documented in the registers of relevant material held by researchers across the establishment. SOP 'HTA-1001 Disposal of human tissue' is written to ensure the disposal method of the samples is documented but it does not ensure that the date and reason for disposal are documented on the sample registers held by researchers.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and fit for purpose		
c) There are documented cleaning and decontamination procedures.	There are inconsistencies in, and lack of, documented cleaning schedules across the entire establishment, in all areas where relevant material is held. There is no documented schedule for the defrosting of freezers in all areas where relevant material is held.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	There is an inconsistency in temperature monitoring across the entire establishment. Some equipment is fitted with digital monitoring systems, and some equipment were monitored manually and daily. However, there was also other equipment with no monitoring at all for samples held at room temperature, -20°C, -80°C and in liquid nitrogen.	**Minor**
d) There are documented contingency plans in place in case of failure in storage area.	There is an inconsistency of contingency plans in the event of failure in storage areas. While it was evident that there were a number of documented local contingency plans at some of the sites, there were other sites where there is no contingency plan or visible named contacts in the event of storage area failure.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.	The establishment is currently reviewing how equipment will be serviced and maintained. There is no service contract currently in place for all the storage facilities across all the sites. In general, freezers were not optimally maintained by staff and some were found to be 'iced up'. There is evidence of a few freezers being challenged to test the accuracy of internal temperature probes (by opening freezer doors). However, freezers fitted with an external alarm system are not deliberately challenged by users to ensure that they are working to required specifications. Freezers that are monitored using only integral temperature probes are not compared to a calibrated temperature probe. There is only one site where temperature trends are reviewed by staff.	**Major**
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.	There is no evidence of a process to report an equipment problem.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to standardise the internal consent seeking procedures in SOP 'HTA-1008-UoL Procedure for consent recording'. This should include the formal training required for those staff seeking consent.
2.	GQ1(a)	Some sites have a quality manual that is specific to their activates. The DI is advised to consider developing an overarching quality manual for HTA activities across all sites.
3.	GQ2(a)	It was evident that there were several REC approved studies, now outside of REC approval, where samples that were not eligible to be stored were being stored under the licence. This was due to: • the absence of consent forms; or • consent forms clearly stating that samples were only to be stored and used for a particular study; or

		• the further storage or use of samples after the study had ended was not stated
4.	GQ3(a)	The DI is advised to keep copies of staff training records and certificates in site master files for all HTA-related activities and training (see good practice comment below).
5.	GQ4(b)	The DI is advised that paper documents relating to HTA activities are stored in fireproof cabinets and to have scanned electronic copies for archived paper documents.
6.	T1(c)	The DI is advised to improve the governance of, and traceability of samples associated with, all REC approved studies. This is important if the intention is to store these samples under HTA licence after the REC approval has expired. The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA's licensing standards.
7.	T1(c)	To raise awareness and facilitate traceability, the DI is advised to consistently use the university template for external signage on all equipment where human samples are stored under the licence.
8.	PFE2(d)	To improve awareness of storage contingency, the DI is advised to consider compiling all the contingency freezer space from each site and to share this across all sites.

Concluding comments

The establishment staff were engaged and acknowledged that, while most of the HTA standards were met, there are a few significant areas that require improvement. Three major and eleven minor shortfalls were identified against the standards across all of the HTA's standards group.

As an example of good practice, it was found that that the PD at Glenfield Hospital had created a 'Site Master File' for all HTA activities, centralising all the necessary documents for the staff working under the licence.

There are a number of areas of practice that require improvement, including three major shortfalls and eleven minor shortfalls, across all the HTA's standards groups.

The HTA requires the Designated Individual 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.

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.

Report sent to DI for factual accuracy: 05/07/2019

Report returned from DI: 22/07/2019

Final report issued: 05/08/2019

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: 20/03/2020

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code 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. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
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. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
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.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
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.
b) A register of donated material, and the associated products where relevant, is maintained.
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.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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 or site visit.

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 both the draft and final inspection report. You 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.