Site visit inspection report on compliance with HTA licensing standards

Liverpool John Moores University

HTA licensing number 12528

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 & 05 April 2018

Summary of inspection findings

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

Although the HTA found that Liverpool John Moores University had met the majority of the HTA's standards, four minor shortfalls were found against standards relating to audit and maintenance records.

Advice has been given around consent training documentation, the quality management system and risk assessments.

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

Liverpool John Moores University (the establishment) is an academic institution licensed for the storage of relevant material for use for a scheduled purpose, principally 'Research into the disorders, or the functioning, of the human body'. The establishment has been licensed by the HTA since 2008. It is noted that the establishment has made significant progress in the last six months with the development of a more robust quality management system.

All relevant material is stored at the Life Sciences Building with the exception of the anthropological collection stored at the James Parsons Building. The anthropological collection consists of skeletal material that is believed to be less than one hundred years old. These specimens are stored at ambient temperature in locked cabinets, which are temperature- and humidity-monitored via data loggers. All specimens have identifiable information attached and are traceable to both the electronic and paper database.

Donors of relevant material are a combination of NHS patients, healthy volunteers recruited from University (staff or students) and, occasionally, athletes. Sample types include whole blood, blood pellets and muscle biopsies. Samples are stored in cryovials in -80°C freezers, except for tissue from frozen sections that is mounted on microscopic slides, which are stored at -20°C.

Project managers and experienced postgraduate students are responsible for consenting donors. Consent seekers receive ethics training and shadow experienced staff before seeking consent themselves. All potential donors are given an information sheet and time to ask questions before consent is sought.

Several projects have received favourable ethical opinions from NHS Research Ethics Committees (RECs) and are therefore exempt from the licensing requirements of the Human Tissue Act 2004 (HT Act). Research projects may be also be reviewed by the University Research Ethics Committee (UREC). Relevant material for research projects which have approval from UREC is stored under the authority of the HTA licence.

Samples remaining after completion of NHS REC-approved projects will either be disposed of or stored under the HTA licence. The establishment is working at strengthening this process (see *Advice*, item 7). The establishment does not differentiate between relevant material and other material, storing everything under the same HTA governance systems.

Description of inspection activities undertaken

This was a routine, and the second, inspection of the establishment; the first inspection was in 2014. The inspection included a visual inspection of the storage areas and the anthropological collection, discussions and interviews with key staff, traceability audits and a review of documentation. Interviews were held with the Designated Individual (DI), the Corporate Licence Holder contact (CLHc), the HTA Coordinator, the Faculty Operations Manager and a Senior Lecturer in Sports Science involved in taking consent.

Forward and reverse traceability audits were performed for four samples, comprising one dried blood sample stored at -20°C, two blood samples and one muscle biopsy in -80°C storage. The samples were randomly selected from different locations within the storage facilities and labelling and location details were compared with the electronic records. There was one minor issue with the muscle biopsy, which was recorded in electronic records as ‘Disposed of’. The discrepancy was resolved by further investigation of the source records. All relevant consent forms were crosschecked for the samples and no anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
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 documents HT-WORK-003 through to HT-WORK-011 are in draft format.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	There is an audit schedule; however, there are currently no routine horizontal or vertical audits taking place. Therefore, there is no assurance that the establishment are routinely auditing licensable activities.	**Minor**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	The establishment are carrying out sample checks of relevant material stored as part of a categorising exercise, however, these checks are not documented appropriately, actioned upon or shared for future learning (see *Advice*, item 4).	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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 freezers used to store relevant material have not been subject to maintenance checks and there are no maintenance records.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2(a)	Students and staff complete training, which includes generic consent training, before their projects begin. They are then trained in seeking project specific consent before seeking consent themselves. However, this training is not documented. The DI is advised to ensure that specific consent training is documented in training records.
2.	GQ1(a)	The DI is advised to remove “Relevant material that is imported is not relevant” from the policy document as this is inaccurate and misleading. In terms of research, the consent provisions of the HT Act do not apply to imported material. However, the HTA considers it good practice for there to be mechanisms in place to provide assurance that the tissue has been obtained with valid consent. Specific guidance on import (and export) is set out in the Code E for Research (published April 2017) paragraphs 98-114.
3.	GQ1(a)	The Quality Manual incorrectly defines the DI as working under the Quality and Safety Regulations. The DI is advised to correct this to the Human Tissue Act 2004.
4.	GQ2(a) (b)	The DI is advised to begin routine auditing as per the audit schedule and to document these findings appropriately. Audit findings need to record details of the audit and corrective and preventative actions taken.
5.	GQ5(b)	Historically, adverse events have been reported and acted on at the establishment. This action was ceased while overhauling the governance and quality systems. The DI is advised to resume reporting adverse events internally and generating adverse events reports. The DI is advised to share these findings and actions at the steering committee meeting and with relevant staff members for future learning.
6.	GQ6(a)	There is a thorough template of risk assessments that staff and students complete prior to starting a project. The DI is advised to include risks associated with consent process to this document.

Concluding comments

There are a number of areas of practice that require improvement, including four minor shortfalls.

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: 02/05/2018

Report returned from DI: 07/06/2018

Final report issued: 07/06/2018

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: 26 July 2018

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.