Site visit inspection report on compliance with HTA licensing standards

University of Westminster

HTA licensing number 12015

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**

23 May 2019

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.

Since the previous inspection, there has been an increase in licensed activities, including the number of samples stored and the number of storage locations. There have also been two changes of DI and a change of Corporate Licence Holder contact (CLHc).

Although the HTA found that the University of Westminster had met a number of the HTA's standards, four major and seventeen minor shortfalls were identified against standards across all four of the HTA's standards groups.

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

The University of Westminster (the 'establishment') is an academic institution that currently has 19,000 students, undertaking undergraduate, post-graduate and professional courses. The establishment also undertakes internationally recognised research that has positive effects on individuals, communities, the environment and economy. The HTA licence covers the storage of relevant material for use for the scheduled purpose of research within the School of Life Sciences and the School of Social Sciences, which both fall under the College of Liberal Arts and Sciences in a recent organisational restructure of the establishment. A number of Persons Designated (PDs) work in both schools. Their research uses relevant material obtained from a variety of sources: projects that have either NHS Research Ethics Committee (REC) approval or University Research Ethics Committee (UREC) approval, research collaborations, research tissue banks (RTBs), and tissue donations from volunteer staff. Consent is sought by individuals from each research group for projects approved by NHS RECs and URECs.

The establishment has been licensed by the HTA since May 2007. This was the establishment's second routine inspection; their first inspection was carried out in August 2010.

Description of inspection activities undertaken

The inspection timetable was developed in 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:

- Fifteen tissue samples stored in -80°C freezers
- Thirteen samples stored as wax blocks and slides at room temperature (RT)
- Five tissues samples stored in -20°C freezers
- Five tissues samples stored in -140°C cryostore

There were inconsistencies and inaccuracies in the sample tracking. Some samples were identified as 'used up' on the sample register, however the samples were present in the freezer. In addition, the majority of samples audited did not have unique codes. Consent forms were available; however, some of these were found to be incomplete. For example, the donor had provided a signature but had not indicated, from the options on the consent form, how they would like their tissue sample to be used.

Inspection findings

The HTA found the Designated Individual (DI) and the Corporate Licence Holder contact (CLHc) 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		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.	Human Tissue Act SOPs is a cluster of SOPs including consent procedures. The consent section is a generic SOP detailing HTA activities and mentions activities that the establishment are not licensed to undertake. C101 is another document covering consent policy and SOP. The presence of several different documents relating to consent presents a risk of inconsistent application of knowledge and/or practices.	**Minor**
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 is an inconsistency and absence of agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and HTA's Codes of Practice. The lack of assurances was particularly evident when researchers received tissue samples from overseas collaborators.	**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 an absence of formal training for staff seeking consent which addresses the requirements of the HT Act and the HTA's Codes of Practice. Informal and undocumented training is provided by supervisors; there is no evidence of the supervisors receiving formal training. *Standards C2(b) and C2(c) could not be assessed.*	**Major**

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 SOPs and procedures are inconsistent in use of template, version number and evidence of up-to-date review and implementation. There are several documents detailing the action plans in the event of power outage, out of range temperatures for freezers and cold rooms, freezer alarms being activated and use and refill of liquid nitrogen tanks. Procedural documents lacked the clarity and consistency expected to enable staff to accurately follow a procedure or process from beginning to end.	**Minor**

b) There is a document control system.	There is a consistent lack of document control, creating the risk that staff are not following the most up-to-date procedure or policy. *Standards GQ1(c) could not be assessed.*	**Minor**
e) There is a system for managing complaints.	Although the Quality Manual (date of last modification 31/03/2019) has a section '5.12 Complaints procedure'. This states the complaint is a verbal notification to the DI. There is an absence of a SOP and/or policy for managing complaints.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	While there is a documented schedule of audits, it is insufficient and does not adhere to the frequency stated in the establishment's quality manual. The audit schedule entry for 'June-July 2019' does not provide details of audits to be conducted or assurance that audits will cover licensable activities.	**Major**
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	There is an 'Audit Reporting Template' with effective date 28/04/2019, version number 1. There is no evidence of a previous audit reporting template. There is no evidence of a detailed audit report. The document 'Schedule of Audit 2010 to 2019' lists two audits undertaken in 2015 and 2017 (no specific dates). The few points of 'actions arising' from both audits do not detail who was audited or how many groups were audited. Some of the 'actions arising' were generalised. The document does not identify specific issues that led to the actions arising.	**Minor**
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.	While there is a 'Records Management Policy' which is an institutional policy approved by the University Executive Board (UEB), it does not provide detail for HTA-related activities to ensure that the establishment have documented records that can be used by the establishment to evidence traceability and ensure a robust audit trail; this policy by itself, is not enough to meet the standard.	**Minor**

b) There are provisions for back-up / recovery in the event of loss of records.	There is an inconsistent provision for back-up and recovery of records relating to all HTA-licensable activities.	**Minor**
GQ5 There are systems to ensure that all adverse events are investigated promptly		
a) Staff are instructed in how to use incident reporting systems.	During interviews with establishment staff, there was a lack of understanding about how to report incidents. There are SOPs for dealing with power outages to -80°C freezers and cold rooms, and alarm activation, but these are for actions to be taken by the operational desk staff. The SOPs do not mention that these incidents should be reported.	**Minor**
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.	There is no evidence that incidents are investigated, corrective actions are taken and preventative actions are implemented to prevent future similar incidents.	**Minor**
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.	There is an absence of risk assessments for the key procedures and practices. *Standards GQ6(b) and GQ6(c) could not be assessed.*	**Major**

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. A single unique code is often used for samples divided into multiple aliquots and multiple samples received from the same donor. This creates the risk of a lack of traceability for all samples from a donor and impairs the ability to identify individual samples. This also impedes 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 is a register of donated material. It was evident that the register was not maintained or up-to-date. There were inaccuracies between several of the samples recorded on the register compared to the actual samples stored.	**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.	During the sample traceability audits that were undertaken, it was identified that the physical storage locations of some samples did not match those recorded on the electronic database. These samples, which had been recorded as 'all used up', were found to still be in storage.	**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.	There were no specific records for disposal of relevant material held under licence. The system used as a sample register of relevant material did not record date, method and reason.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		

a) There is sufficient storage capacity.	There are many freezers used to store samples for HTA-licensable activities. As part of the contingency plan, some of these freezers have been allocated as 'a dedicated empty freezer space'. During the inspection, it was evident that these dedicated empty freezer spaces were not empty. In addition, these dedicated empty freezer spaces were not monitored to be kept empty as part of the contingency plan.	**Minor**
c) Storage conditions are monitored, recorded and acted on when required.	There are inconsistent monitoring systems for both temperature and/or alarm activation. Some storage locations have no temperature monitoring.	**Minor**
d) There are documented contingency plans in place in case of failure in storage area.	The establishment has an agreement with another institution for the sharing of facilities in the event of equipment failure. The details of this agreement are unclear and need to consider the risks to the samples during transport.	**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. Freezers were generally not maintained by staff and were found to be heavily 'iced up', The alarm temperature trigger points varied across all freezers and users were not always familiar with the accepted normal temperature ranges. This creates a risk that deviations from the expected normal temperature ranges may not be identified by users. Alarm systems are not deliberately challenged by users to ensure that they are working to required specifications. Temperatures are monitored using only the integral temperature probes of the storage units and are not compared to a calibrated temperature probe. The temperatures of all storage units are not monitored out of hours or reviewed for trends.	**Major**

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 ensure that all staff seeking consent are trained to check that all consent forms are completed to required expectations.
2.	GQ1(d)	The DI is advised to consider increasing the frequency of the biannual meeting of the HTA Steering Group (HTASG). This may enable more frequent discussion of matters relating to HTA-licensed activities. The DI is also advised to consider whether there is a useful role for a regular meeting that involves the PDs.
3.	T2(a)	In terms of disposal, the HTA recognises that what is sensitive and what is feasible at local level needs to be taken into account. As set out in the HTA's code of practice relating to research, the DI is advised that it is good practice for human tissue to be bagged separately from clinical or other laboratory waste. The DI is advised to bring this to the attention of all staff working with relevant human material and amend the SOP 'Disposing of tissue' to reflect this practice.
4.	PFE2(c)	Periodically, the DI is advised to look for any potential storage temperature trends which may give an early indication of failing equipment.

Concluding comments

The establishment staff were engaged and acknowledged that, while some of the HTA standards were met, there are a significant number of areas that require improvement. Four major and seventeen minor shortfalls were identified against standards across all of HTA's standards groups. Some of these shortfalls were a result of non-compliant findings not addressed by the establishment after their previous inspection in 2010. In addition, there has been an increase in HTA-licensed activities and areas of storage following the last inspection.

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: 25/06/2019

Report returned from DI: 09/07/2019

Final report issued: 23/07/2019

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: 23/12/2020

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.