Site visit inspection report on compliance with HTA licensing standards

Cardiff Metropolitan University

HTA licensing number 12408

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**

24 & 25 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 Cardiff Metropolitan University had met the majority of the HTA's standards, one minor shortfall was found against the Traceability standards. There has been a marked improvement in meeting standards since the last inspection.

Particular examples of good practice are included in the concluding comments section of the report.

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

Cardiff Metropolitan University (the establishment) is licensed under the Human Tissue Act 2004 (HT Act) for storage of relevant material for use for scheduled purposes. This licence applies to the Llandaff Campus (hub site) and the Cyncoed Campus (satellite site).

The establishment has been licensed by the HTA since June 2007. This report describes the third, routine site visit inspection of the establishment. The Cardiff School of Health Sciences, currently located at the hub site, has merged with the School of Sport, which is based at the Cyncoed Campus. The resultant Cardiff School of Sport and Health Sciences continues to be on two separate campuses but the process of merging the location is going through the development phase and systems and processes as well and facilities are being put in place to facilitate the changes.

The establishment stores relevant material for the scheduled purposes of 'research in connection with disorders, or functioning, of the human body' and 'education or training relating to human health'.

Research

The majority of samples stored under the HTA licence are stored for use for research. At the time of the inspection, the establishment was storing samples in connection with 17 research projects. Samples which are not considered to be relevant material, such as serum or plasma which have been prepared in a manner to render them acellular, are stored under the licence to ensure compliance with the standards set by the HT Act. Under the same governance, the establishment also stores samples with approval from a recognised research ethics committee (REC) which are exempt from the licensing requirements of the HT Act.

The establishment requires all researchers to notify the DI of their intention to store human tissue/ cell samples at the establishment, whether or not the storage is exempt from the licensing requirements of the HT Act. The Designated Individual (DI) - or the Person Designated (PD) at the satellite site - maintains a record of all research projects collecting and/or storing human samples. The establishment requires that researchers obtain approval for use of human samples for research from one of the University's ethics committees, unless they have approval from a recognised REC. Researchers are required to maintain a project file containing paper records of key documentation relating to human samples collected, stored or transported to/from the establishment.

Staff and students seek consent for the collection, storage and use of samples for research. Consent training is provided by the DI. Completed consent forms are stored in project files and are audited regularly for completeness.

Samples may be received from organisations both within and outside of England, Wales and Northern Ireland. Researchers are required to obtain approval from the DI for samples to be transferred and stored under the licence. The approval process includes checks on material transfer agreements with organisations supplying samples to provide assurance that consent has been given in accordance with the regulatory requirements. The establishment transfers samples to other organisations. Researchers are required to obtain approval from the DI for distribution of samples stored under the licence. The approval process includes checks on material transfer agreements with organisations receiving samples to provide assurance that samples will be stored and used in accordance with the consent given. Records of transport and agreements with third party organisations supplying or receiving samples are stored in project files.

Samples are stored securely under the licence in -80°C freezers, 4°C refrigerators or in a liquid nitrogen storage tank. Storage temperatures of the freezers and the refrigerators are continuously monitored and there are automated alarms with call-out notification procedures in the event of deviations from the acceptable temperature ranges. The establishment conducts periodic tests of the temperature alarm call-out systems. Temperature alarms and freezers are serviced regularly. Liquid nitrogen levels are monitored weekly and filling of the liquid nitrogen tanks is recorded, but the tank is not alarmed to alert when liquid levels fall below an acceptable level. The establishment has carried out a risk assessment on the lack of an alarm system in place. The establishment has contingency arrangements for storage in the event of equipment failure.

All samples stored under the licence are assigned a unique identification number or name, which is used to track sample receipt, storage, use, distribution and disposal. The establishment uses an electronic database to provide traceability of samples. The DI and PD at the hub site conduct regular traceability audits of samples in storage.

Education and training

The establishment stores material from the living for use for education and training. At the time of the inspection, the establishment was storing one collection of microscope slides (existing holdings) and one refrigerated collection of acellular plasma at the hub site for use for education and training. These are exempt from the licensing requirements of the HTAct.

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 included a visual inspection of the areas where samples are stored under the licence, sample traceability audits, review of documentation and interviews with staff working under the licence. Although no relevant material was stored at the satellite site at the time of the inspection, the inspection team visited the Cyncoed campus to inspect the storage of consent documentation relating to relevant material stored at the hub site and to view areas where material may be stored in the future.

Audits of sample traceability were conducted for nine projects from research groups with samples stored under the licence. These audits included forward and reverse audits between samples and traceability records for each collection and included disposal records where relevant. These audits revealed an anomaly in traceability in one set of buffy coat samples for one project (see shortfall against standard T1(c)). Full sample traceability was demonstrated in the audits of the samples stored by the other eight research groups. Audits of sample traceability were also conducted for both collections stored for education and training. Consent forms were audited for three projects. Two minor anomalies were found (the consent forms were not fully completed) which were corrected at the time of the inspection (donors were re-consented and the forms fully completed)

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

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		
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.	At the time of inspection, the location of samples stored within one storage box from one research group was not recorded on the electronic database.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(d)	The DI is advised that donors should be asked in the consenting process, and their decision documented, about whether they wish to be informed about any health-related findings identified through the research analysis (see paragraph 34 of Code of Practice E).
2.	GQ1(d)	Currently, scheduled HTA Committee meetings are held for senior staff. The DI is advised to introduce periodic HTA-related governance meetings for all staff working under the licence to help to ensure that they are aware of important information relating to activities conducted under the licence. These could include audit findings and timeframes for the completion of actions, and information from the HTA.
3.	GQ1(d)	The DI is advised to appoint additional PDs in the School of Health Sciences to ensure oversight of all activities conducted under the licence.
4.	GQ2(a)	Currently, audits of HTA-related activities are performed by the PDs and the DI only. The DI is advised to encourage principal investigators/research groups to

		audit their own licensed activities to assess compliance with HTA standards. The DI may wish to encourage external audits whereby research groups audit each other's activities for compliance.
5.	GQ2(b)	Audit findings and corrective and preventative action (CAPA) plans are discussed and closed at the HTA Committee meetings. The DI may wish to discuss these findings at meetings suggested in *Advice*, item 2. This will provide a shared learning opportunity for staff working directly under the licence and enable any trends in non-conformities to be identified and CAPAs discussed.
6.	GQ4(b)	The original participant consent forms are stored in the project files. The DI is advised to scan these forms to an electronic database to ensure back-up in the event of a loss of paper-based records.
7.	T1(c)	Samples are currently stored at -40°C at the satellite site pending transfer to the hub site. The DI is advised to reinstate the sample inventory at the satellite site to record the time of transfer of the sample(s) and the person transporting the sample(s). This will ensure full traceability is maintained.
8.	PFE3(c)	The establishment is advised to ensure that all staff have easy access to, and wear, appropriate personal protective equipment (PPE). Whilst PPE was available at the establishment, staff accessing storage areas did not always wear this.

Concluding comments

Staff at the establishment have strived to make improvements since the last inspection. They work together as a team and appear to communicate well. Many good practices and strengths were seen during the inspection including the following:

- All human samples, whether held under the HTA licence or under a recognised REC, are held under the same governance. This ensures a consistent approach to storage of human tissue for research.
- There is a thorough, three-stage training process for consent seekers. An audit is performed when individuals seek consent for the first time and advice and feedback is given to improve consent-seeking practices.
- Access to the laboratories is only given to researchers when they have completed the 'Knowing your responsibilities' training in human tissue.
- The PD at the hub site has received external training in auditing procedures and practices, and has worked closely with the DI and PD at the satellite site to conduct a wide range of audits relating to the HTA licence.
- There are Project Boxes in place in which researchers maintain key details relating to their study. This helps to assure the DI that the necessary information relating to the studies that are being undertaken at the establishment are consistently recorded and maintained.
- There is a comprehensive suite of risk assessments against all licensable activities.

There is one area of practice that requires improvement where a minor shortfall was identified against a traceability standard. Advice and guidance was also given in relation to consent, governance and quality systems and premises, facilities and equipment.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 23 May 2018

Report returned from DI: 31 May 2018

Final report issued: 4 June 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: 24 October 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.