Site visit inspection report on compliance with HTA minimum standards

Brunel University London

HTA licensing number 12543

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**

27 September 2016

Summary of inspection findings

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

Although the HTA found that Brunel University London (the establishment) had met the majority of the HTA standards, two shortfalls were found in relation to the Governance and Quality systems (GQ) and Premises, Facilities and Equipment (PFE) standards. The shortfalls were in relation to staff training and incomplete critical equipment monitoring. Advice has been given on a wide range of matters covered by the Consent, GQ and PFE standards.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at Brunel University London (the establishment). The establishment is licensed for the storage of relevant material for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The establishment has been licensed since 2009 and was last inspected in July 2009. This inspection was the second routine site visit inspection.

The DI is the Health, Safety and Environmental Officer (Science and Environment), Human Tissue Risk and Compliance Officer and the Radiation Protection Officer. The Corporate Licence Holder is Brunel University London and the Corporate Licence Holder contact is the Secretary to Council and University Secretary. There are three Persons Designated (PD) under the licence.

The establishment is comprised of three colleges; the College of Health and Life Sciences, the College of Business, Arts and Social Sciences and the College of Engineering Design and Physical Sciences. Each college has its own local research ethics committee (REC) and all research project proposals must be reviewed by a REC. Applications are submitted using

the establishment's online research application system, Brunel Research Ethics Online (BREO). Where appropriate, the REC can refer an application to the University REC (UREC) for consideration. All research projects using human tissue must be approved by the UREC, which in turn reports to the University Senate on a regular basis. The DI also reviews all applications for research using human tissue.

A Human Tissue Committee meets four times a year to discuss matters pertaining to human tissue. The agenda and minutes of these meetings are made available to students and staff on the establishment's intranet.

The establishment's human tissue collections are held in the College of Health and Life Sciences. At the time of inspection, the majority of human tissue samples are held in the Sports Science Department. These samples included whole blood, plasma, urine, saliva and sweat. Samples are obtained from healthy volunteers, who are recruited at the establishment. Researchers who seek consent from volunteer donors attend mandatory consent training. Volunteer donors are provided with patient information sheets detailing the study. Samples are securely stored in -80°C freezers, which are monitored either directly or indirectly by a PD.

Samples held in the Biosciences Department are predominantly histological slides, obtained before the introduction of the HT Act, and are used for teaching purposes. There are also a number of other samples, including embedded material for electron microscopy and a number of bone marrow samples, as well as a skeleton. A PD has oversight for this collection and provides researchers using the material with training on storage and disposal. Samples are stored at room temperature, -20°C and -80°C.

In addition, a number of bones are stored in the Clinical Sciences Department for teaching purposes. The bones are stored in a locked cabinet and a log book is used to maintain traceability.

At the time of inspection, the majority of stored samples had been sourced from within the United Kingdom, with a number of samples originating in the United States. The HTA understands that samples which had previously been obtained from Crete were disposed of a number of years ago, records of which were seen during the inspection.

At present, a spreadsheet is used to record the number of samples in storage; however, new proprietary software is being introduced in the coming months which will allow for online, real-time recording of samples.

The inspection comprised of a roundtable discussion with all members of staff working under the licence, a visual inspection of the areas where human tissue is stored, interviews with the Chair in Exercise & Cardiovascular Physiology (PD), the Reader in Biosciences (PD), Corporate Licence Holder contact, the Designated Individual (DI) and a review of governance documentation.

In addition, traceability audits were carried out using four tissue samples stored at -80°C. Samples were identified from their storage locations and traced to relevant documents. No discrepancies were found.

Inspection findings

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

Compliance with HTA standards

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.	The HTA has been assured that staff are provided with training in seeking consent, the HTA and the HT Act as part of the establishment's induction. However, the training provided appears to be inconsistent and records are not located in a centralised system, making it difficult for the DI to ensure staff are suitably trained. The materials and resources available to support staff on what is required under the HT Act and the HTA licensing framework are currently found on the health and safety area of the intranet and are not clearly signposted.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Relevant material is stored in two -80°C freezers, with an additional back-up freezer available. The two freezers used to store relevant material are located in different areas within the establishment and there are inconsistencies in the monitoring systems. One freezer is connected to a remote call out system; however, this does not extend to the second or contingency freezers. The second freezer contains valuable samples from children with a rare genetic disorder. Temperature checks are not regularly documented for the second and contingency freezer, which means the establishment is not able to trend temperature changes in order to identify potential freezer failure. The freezers are not connected to a back-up system (either power or CO_2). In addition, they are located in different areas within the establishment and are not covered by the nightly security patrol, which in the absence of a call-out system would alert staff to freezer failure. Although no issues relating to equipment failure have arisen, the establishment has not risk assessed the current arrangements for monitoring temperatures in order to ensure that tissues are stored under suitable conditions.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	Consent training is mandatory for new members of staff; however, in the documents reviewed, there was no reference to the HTA's Codes of Practice. The DI is advised to review the documentation to include reference to the relevant HTA Codes of Practice and to ensure staff are aware of the latest guidance from the HTA.
2.	GQ2	While there are documented policies and procedures in place, the system to ensure version control should be strengthened. For example, the Research Integrity Code of Practice 2016 references 12 appendices, each with different review dates; these documents were also issued as independent documents.

3.	GQ2	Material transfer agreements were provided to the HTA inspection team but these agreements were not version-controlled. The DI is advised to review the documents regularly and include version control to ensure the most up-to-date versions are being used.
4.	GQ2	The DI maintains a regular and robust audit schedule. Although the findings and actions are discussed at the regular Human Tissue Committee meetings, they are not recorded in a corrective and preventative action plan. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.
5.	GQ4	The DI is advised to draft an SOP detailing the procedure for records management, including reference to the creation, amendment, retention and destruction of records. As research projects which are no longer under NHS-REC approval fall under the remit of the HTA licence, it is important that the DI monitors project expiry dates. The DI should consider how a reminder function could be incorporated into the new database tracking system for samples, which can be used to alert the DI of samples being stored for NHS-REC-approved projects nearing expiry.
6.	GQ6	At the time of inspection, it was difficult to link consent forms with the relevant participants because of the current filing system. The DI is advised to consider how the existing system could be improved to enable consent forms to be more easily linked with samples to ensure traceability.
7.	GQ8	All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining. Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities. A range of risk assessments are described in the Brunel University London Code of Practice on working with Human Tissue Samples but the DI is advised to consider the following additional areas of risk: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • loss of human tissue; • incorrect disposal. Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident. By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.
8.	PFE3	The establishment also stores non-human material. To avoid the risk of sample confusion, and to ensure that human tissue samples are handled in line with the

		regulatory requirements under the HT Act, the DI should assure himself that all freezers and containers holding human tissue are labelled appropriately.
9.	PFE4	In the past, the establishment has received tissue from overseas. While this is not currently the case, there is a possibility that this will resume in the future. The DI is advised to consider relevant HTA guidance and evaluate pertinent associated risks.

Concluding comments

During the inspection, areas of good practice were noted:

- There is a Human Tissue Committee, comprising the DI, the CLHc, the Director of Research Ethics and Governance, the PDs and other senior staff, which meets on a quarterly basis
- The DI has implemented new systems and procedures since taking over the post in July 2015 and is introducing a new tracking system for recording samples.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to improving documentation systems for consent, document version control, updating SOPs and risk assessments, as well as to licence management.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 24 October 2016

Report returned from DI: 7 November 2016

Final report issued: 10 November 2016

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place

- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately
• Documented risk assessments for all practices and processes • Risk assessments are reviewed when appropriate • Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination • Appropriate health and safety controls are in place
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination • Contingency plans are in place in case of failure in storage area • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis • Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transport • Records of transportation and delivery • Records are kept of any agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

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.