Site visit inspection report on compliance with HTA minimum standards

Aston University

HTA licensing number 12381

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**

11 March 2015

Summary of inspection findings

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

Aston University (the establishment) was found to have met all HTA standards.
Advice has been given relating to the Governance and Quality Systems (GQ), Premises, Facilities and Equipment (PFE) standards.

Particular examples of 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 1st November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The majority of the work carried out by the establishment is undertaken under phase I or II of a clinical trial and has recognised United Kingdom Ethics Committee Authority (UKECA) and therefore the tissues are exempt from the HTA licensing requirement.

The establishment stores approximately 3000 samples under twelve clinical trials. Materials currently being stored include: placenta, myometrium, breast tumour tissue, sarcoma tissue, urine, whole blood, and adipose tissue. Mainly, these samples are frozen but the establishment also stores some fixed blocks and slides at room temperature. The establishment uses electronic databases and paper-based records to provide traceability of samples. All samples are assigned a unique identification number which is used to track sample receipt, storage, release for use in research and disposal. Samples are stored in dedicated storage facilities in secure locations. Freezer temperatures are continually monitored and there is an alarm with a robust call-out notification procedure in the event of a deviation from the set acceptable ranges. Freezers and temperature monitoring probes are regularly maintained and calibrated and the establishment has contingency arrangements for storage in the event of equipment failure.

The establishment has been licensed by the HTA since March 2007. This report describes the first, routine, site visit inspection of this establishment. This site visit inspection included a 'round table' (group) discussion on the human samples being stored, visual inspection of the premises including the storage areas, a review of documentation and meetings with establishment staff. The inspection team conducted interviews with the DI, Corporate Licence Holder Contact and the Chief Technician.

An audit of stored samples and traceability records, including electronic databases and storage locations, was conducted for the samples stored in the three -80^{o}C freezers. All samples were chosen at random by the inspection team. No anomalies were identified with the traceability of the samples.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to review the Terms of Reference of the HTA Governance Group to ensure that the current membership is accurately reflected.
2.	GQ2	The establishment follows the University Waste Collection department's standard operating procedure (SOP) when disposing of tissue which allows for separate bagging and disposal of animal and human tissue. The SOP was past the review date stated in the document control (SOP SP6.1). The DI is advised to ensure that the disposal procedure followed is current and may wish to establish a process with the Waste Collection department to be alerted of any changes to the University's process and SOP.
3.	GQ2	As part of the clinical trials work, the establishment conducts audits of clinical practices. The DI explained that in the near future, when samples are to be transported from the local hospitals under a Material Transfer Agreement (MTA), the DI will be auditing the consent procedures and records at the site where the donation happens. The DI is aware of, but has not developed, a schedule of HTA audit requirements, as the samples fall under the remit of clinical trials. The DI may wish to implement audits now so that there is a process in place for when samples fall under the HTA licence. The DI should consider conducting audits internally and ensure that these are

		documented. The audits could cover aspects related to storage, record keeping and disposal. Corrective and preventative actions should be taken where issues require resolution, and these should be documented and discussed at the HTA Governance Group.
4.	GQ4	The establishment uses both a paper-based records and an electronic system to store data. The electronic system is backed up centrally but there is no back-up of the paper-based system. To improve traceability, the DI may wish to consider introducing an excel spreadsheet which could be used to capture those samples that will be processed/used and disposed of on the same day.
5.	GQ5	Other licensed establishments have set up a register of 'approved suppliers'. Each potential supplier is sent a 'due diligence form', asking for details of governance structure, ethical approval, ethical warranties, informed consent forms, consent warranties and regulatory compliance (where appropriate). A Material Transfer Agreement (MTA) is then drawn up with each organisation using these criteria as the supplier's responsibilities. Similar MTAs with receiving organisations are also used. The DI is advised to consider adopting such a method.
6.	GQ6	The establishment has a standard template MTA in place for all the samples brought in from other establishments. The DI has developed a new MTA template with the University Legal Services Department. It was noticed that one of the MTAs appeared to be out of date. The DI is advised to introduce a system which ensures either that all MTAs are within date, or are perpetual, and can only be ended by one of the parties by giving the required notice. The DI is advised to review and add a statement to this effect to the agreement and/or related SOP/documents.
7.	GQ7	The establishment has systems in place to ensure that all adverse events are recorded in a central log and are investigated promptly. However, the incidents log did not record an event within the last year where there was a total power cut across the university when power to all the freezers had cut out. The DI may wish to refine the definition of an adverse event so that the categories of a reportable incident are clear; how they will be monitored and ensure that all staff are aware of the incidents which need to be reported. The results of all actions taken (root cause analysis and corrective and preventative actions) should be formally recorded and reviewed by the HTA Governance Group. The establishment may wish to introduce a standard form for incident reporting or use the facility available on their electronic database system.
8.	GQ8	There are risk assessments relating to Control of Substances Hazardous to Health (COSHH) in relation to laboratory procedures and Health and Safety. There are no risk assessments for licensable activities, which would be relevant where there is a future need to store tissue under the licence.

		Although not exhaustive, the DI should consider the broad risks to relevant material, such as: • specimen loss • missing or incorrect documentation • security breach • abnormalities in storage temperature readings • specimen transport between sites under this licence or to other licensed establishments and • inappropriate disposal Risk assessments should be reviewed regularly and also after changes to key procedures. The DI is advised to ensure that staff have access to such risk assessments and that familiarity with them is incorporated into the staff training programme.
9.	PFE3	All freezers storing human tissue are subject to an external temperature monitoring alarm and some have a callout system. The DI is advised to implement the same system for all freezers and to carry out regular testing of the tissue storage alarm system to ensure that the callout procedure is functioning correctly. Until the system is fully in place, the fridges/freezers should be closely monitored by staff.
10.	PFE3	An external company maps and keeps a log of the freezer temperature. The DI is advised to initiate a program by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs.
11.	PFE3	In addition to human tissue samples, the establishment also stores some animal tissues in separate freezer compartments and in storage cupboards. The DI is advised to conduct an audit of samples held to be clear as to the type of sample (animal-vs-human) and to ensure that all freezers and cupboards which contain human tissue are appropriately labelled. The DI should ensure that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups.
12.	PFE5	The freezers are cleaned and there is a supporting SOP in place. However, there is no SOP for decontamination. The DI is advised to implement processes for the regular decontamination of all freezers and cupboards containing human tissue and to ensure that records of this are kept up to date. This may take place prior to servicing.

Concluding comments

This report outlines the first routine HTA site visit inspection of Aston University. There were a number of areas of good practice observed during the inspection. The establishment has a commitment to the continual improvement of practices and compliance with the HT Act. The DI is well supported by the Corporate Licence Holder Contact and other staff. Together, they have

a good oversight of the activities undertaken at the establishment. Although the samples currently stored and used in research are all covered by UKECA approval, the establishment maintains traceability of these samples in the -80^{o}C freezers to the point of use or disposal. All equipment is well maintained and under service contracts. The establishment has a good database system that tracks all the ethics projects and MTAs. A 'delegation of duties' list is drawn up for and associated with each project, identifying the key staff involved at each stage from consent to end use/disposal. The DI has provided HTA specific training and all staff have attended the Good Clinical Practice training. The establishment has a good Quality Manual and Quality Management System in place that is used to continually improve the services they offer. Ethical behaviour is encouraged throughout the organization and is part of the training at induction. The DI reported good support from Vice Chancellor and Pro Vice Chancellors.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 7 April 2015

Report returned from DI: 30 April 2015

Final report issued: 18 May 2015

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.