Site visit inspection report on compliance with HTA minimum standards

Manchester Metropolitan University

HTA licensing number 12402

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**

12 February 2013

Summary of inspection findings

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

Manchester Metropolitan University was found to have met all HTA standards.

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

Manchester Metropolitan University (MMU) stores human tissue at the All Saints Campus (hub) and Crewe Campus (satellite) under a hub and satellite arrangement. The majority of research, which involves human tissue from healthy volunteers, is subject to ethical review by the establishment's internal Academic Ethics Committee. The establishment's HTA Steering Committee also provides oversight of licensable activities that take place across the hub and satellite sites.

The healthy volunteers are mostly students based at the University, who are recruited and consented locally by researchers who have received consent training. The establishment stores several types of relevant material from the living including; blood, buffy coat, buccal cells, as well as skeletal muscle cells. The establishment also stores bone fragments and slides containing tissues from the deceased which are classed as 'existing holdings' as they were obtained and stored before the HT Act came into force.

At the time of the inspection, the establishment was not involved in any research involving human tissue from hospital patients. Material is not transferred between the hub and satellite sites. The establishment has joint research projects with universities based in Europe and so occasionally imports material from outside of the UK which are covered by appropriate material transfer agreements that cover details of appropriate consent and the use of the material for specific research projects.

The satellite site stores human tissue in one -20^{0}c freezer located in a designated room in the Department of Exercise and Sports Science. The hub site stores human tissue in two -80^{0}c freezers located in a designated room based in the the Healthcare Science Research Institute. Both sites have adequate contingency arrangements in the event of freezer failure as well as an auto-dialling alarm system which alert appropriate staff in the event of a freezer failure. Both storage areas have controlled access which is restricted to researchers storing human tissue, with freezers securely locked when not being accessed.

This was the first routine inspection of the establishment. The inspection comprised of a visual inspection, document review and traceability audits including written records and computer records at both the hub and satellite sites. Interviews were conducted with the Designated Individual as well as the Persons Designated at both the hub and satellite sites. An audit trail of three samples was conducted at the satellite site and two samples at the hub site against their respective storage locations and consent forms and information leaflets provided to the volunteers. One of the samples audited was a bone fragment along with associated paperwork from a deceased person, donated before 1st September 2006. No discrepancies were found during the audit trail.

Inspection findings

The HTA found the Designated Individual 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.	C1	Although the establishment uses a consent form that is an approved template which is available to all researchers, the current format does not include options for future use or disposal of samples. The establishment confirmed that it is unlikely that any tissue remains after the research has finished as it is normally all used with little or no surplus material remaining. Nevertheless, the DI is advised to re-consider the current format so that it is clear to the researcher whether a sample can be stored for future research or whether the participant's wish is for the sample to be disposed of after the research is complete.
2.	GQ1	The establishment has a quality manual which covers consent, storage and disposal of human tissue. At the time of the inspection this was in draft and was awaiting review and approval by the Academic Ethics Committee. The DI may want to consider adding a column on the back of the manual so that relevant staff that have read the quality manual can sign it. This will provide assurance to the DI that appropriate staff have read the approved document.
3.	GQ5	The establishment imports human tissue from countries outside of the UK. Whilst the establishment ensures that material transfer agreements (MTAs) are in place prior to importing material, currently the MTAs do not clearly define which samples are associated with a particular MTA. The DI is advised to integrate the review and oversight of MTAs into the HTA steering committee. This will enable more robust traceability of imported material.
4.	GQ6	At the time of the inspection the establishment was in the process of cataloguing a large number of microscope slides containing brain tissue which are classed as existing holdings.These slides are stored in a secure location and are not being used for research purposes. The DI is advised to approach a brain bank to see if they are interested in cataloguing and using the slides. If the microscope slides are not to be used for a scheduled purpose, the DI is advised to dispose of them.
5.	GQ8	Risk assessments surrounding health and safety and human tissue storage are in place. Although there is a good range of risk assessments, the DI is advised to extend the scope of the current risk assessments to include the risks associated with loss of samples and loss of traceability. By extending the scope of the risk assessments this will enable the establishment to consider risks associated with non-conformance to HTA

		standards.
6.	PFE3	<u>Temperature monitoring and signs on freezers</u> All freezers are appropriately alarmed and have an auto dial system in to notify appropriate staff in the event of freezer failures. There are appropriate contingency arrangements in place to deal with freezer failure at both sites. Currently establishment staff will visually check the freezer temperatures but do not record the temperatures in writing. The DI is advised to consider the following: a) Introducing regular temperature monitoring of the freezers which should be recorded in writing. This will enable the establishment to carry out a trend analysis on the temperatures observed. b) Placing signs on the freezers that define the alarm set points for the temperature ranges so that all staff that have access to the freezers are visually reminded of the minimum and maximum temperatures of the freezers.
7.	D1	The establishment has a clear disposal policy as well as a disposal SOP. During the visual inspection at the satellite site it was noted that the current practice for disposal is for researchers to place the material for disposal on the bottom shelf of the freezer. There is a sign on the freezer with instructions for researchers wishing to dispose, however the sign does not request for tissue to be marked 'for disposal'. This may pose a risk of inadvertent disposal of research samples that are placed in this section of the freezer in error. The DI is advised to review the current disposal procedure at the satellite site and review the current sign on the freezer.

Concluding comments

The establishment has worked hard to ensure oversight of human tissue storage and use across both the hub and satellite sites. There are appropriate governance structures in place as well as appropriate systems to ensure that researchers are aware of the HTA's regulatory requirements. An example of this is the HTA Steering Committee where the DI, PDs and relevant staff discuss HTA related activities.The PDs are responsible for security of storage areas and ensure that access to human tissue is restricted to researchers. The establishment uses sample tracking software system at the hub site and plans to introduce this system at the satellite site, which is currently using a paper based system to record sample information. As the amount of human tissue storage increases over time, the establishment aims to use a bar code system to track samples from storage to disposal.

A number of examples of good practice were observed during the inspection. The Academic Ethics Committee will only review human tissue research if reseachers provide evidence that they have completed the Medical Research Council's e-learning module 'Research and Human Tissue Legislation'. The establishment maintains a log of researchers who have completed the e-learning and they are asked to refresh their training after two years. The DI is proposing to devise a consent training programme to be made available to researchers involved in human tissue research. Another area of good practice is the establishment's approach to audits. The establishment carries out audits that focus on completion of records such as, consent forms for each research group. Non conformances that arise from the audits are reported directly to the researcher along with corrective and preventative action plans.

Report sent to DI for factual accuracy: 12 March 2013

Report returned from DI: 2 April 2013

Final report issued: 2 April 2013

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.