Site visit inspection report on performance against HTA quality standards
University of Manchester
HTA licensing number 12172

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

16 & 17 February 2011

Executive Summary

A site-visit inspection of the University of Manchester was carried out by the HTA on 16 and 17 February 2011.

The establishment was found to have met all of the HTA standards. Examples of strengths and good practices are included in the concluding comments section of the report.

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

All reports of HTA site-visit inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

HTA licence 12172 covers the storage of human tissue at the University of Manchester. The tissue collections include 27 individual collections and five Research Tissue Banks (RTBs) which have NHS Research Ethics Committee approval. The collections are housed in the Stopford Building, the Core Technology Facility, the Incubator Building, the Coupland III Building, the A.V. Hill Building, the Michael Smith Building and the Gas and Liquid Nitrogen Building. The buildings are located in close proximity to each other and accommodate laboratories within the Schools of Biomedicine, Pharmacy, Life Sciences, Translational Medicine, Cancer and Enabling Sciences, Community Based Medicine, Dermatological Sciences, the Dental School and two commercial establishments.

The five RTBs are

- the Scleroderma and Reynaud's Tissue Bank,
- the Spinal Inter-Vertebral Disc Tissue Bank,
- the Early Pregnancy Collection,
- the Repository for Rheumatoid- or Osteoarthritis Synovium and
- the Manchester Skin Health Biobank

All of these RTBs store relevant material from living persons. The University of Manchester also houses a Motor Neurone Disease Tissue Bank, which stores tissues from the living in order to extract DNA. The Myositis Tissue Bank was not inspected as it had not yet begun to collect tissues.

The collections contain over 60,000 samples of human tissue from the living and the deceased, including a formalin-fixed whole heart, wet frozen tissue, whole blood, cell suspensions, paraffin-embedded tissue blocks and tissue sections mounted on slides. Tissues are stored in liquid nitrogen, -80°C freezers, -40°C freezers or at room temperature, as required. All tissues are stored under secure conditions.

A site-visit inspection of the University of Manchester was carried out on the 16th and 17th of February 2011. This was the first site-visit inspection of the establishment since it was issued an HTA licence in 2007 and the inspection was classified as 'routine'.

The site-visit inspection included the visual inspection of 24 tissue collections and all five RTBs. Interviews were conducted with the Designated Individual, the Associate Vice President for Research Integrity (who is the Corporate Licence Holder Contact, CLHC), a Research Policy Officer and Persons Designated who oversee tissue collections in Community Based Medicine, the School of Biomedicine, the School of Translational Medicine and one of the commercial establishments.

Research governance at the establishment is overseen by the Office of Research Integrity, the Designated Individual and Persons Designated (PDs) under the licence who are responsible for policies and practices relating to human tissue and monitor adherence to HTA standards.

Individual researchers do not seek consent from donors. Consent is taken by third parties such as clinicians, research nurses and study co-ordinators. There are agreements in place with other establishments, including commercial companies based overseas, to ensure that consent is in place for tissues received into the collections. Staff who transport tissues

confirm that consent is in place before they transport donated tissues to the University. The Motor Neurone Disease Tissue Bank, which stores DNA, has formal agreements in place with third parties who take consent for DNA analysis

A document review was carried out. Documents reviewed included (list not exhaustive): laboratory master files for several tissue collections and RTBs, policies, guidance documents and standard operating procedures (SOPs), records of tissue holdings, temperature monitoring records, audit schedules, audit reports, risk assessments, contingency arrangements, maintenance agreements and training records.

An audit trail from computer records to storage location or disposal record was carried out for randomly selected samples from almost all of the tissue collections held under the HTA licence. Three minor discrepancies relating to traceability records of relevant material on slides were noted but these were not serious enough to be classified as shortfalls and the HTA has provided advice (see below). There were no other discrepancies. The laboratories kept records of the movement of tissues between collections kept at different laboratories.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

For this establishment all HTA standards were met.

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ2	The establishment has an audit schedule which covers consent, traceability, disposal, document control and records relating to tissue collections. The PDs complete HTA Quarterly Performance Management reports which include audits of relevant material stored under the licence. Given the minor discrepancies identified during the audit trail exercise, the DI is advised to remind PDs that these audits should cover stained and unstained slides in each.

Concluding comments

Overall, the HTA is satisfied that the premises and the practices undertaken under the licence are suitable. During the inspection, the HTA observed several areas of good practice.

There is a very good system of governance relating to the management of tissues stored under the HTA licence. The University has an Associate Vice President for Research Integrity, who liaises with the DI and is the CLHC for the HTA licence. The DI and 17 PDs responsible for tissue holdings listed as of 3rd February 2011, have completed HTA on-line training. There is excellent communication between the CLHC, the DI and staff involved in licensable activities. All persons working under the licence are well supported by Research Policy Officers, who provide advice to researchers.

The Office of Research Integrity issues policies and SOPs, as well as templates for material transfer agreements, audit schedules, audit reports, risk assessments, and templates to document tissue collections. These templates are used by each PD to document tissue collections, local practices and procedures, audits and training records, which are filed in laboratory master files. These files document tissue collections that come under the HTA licence as well as those currently covered by NHS-REC approval. This system ensures that the Office of Research Integrity is aware of all tissue collections and can manage the transfer the collections to licensed holdings once the NHS-REC approval lapses.

The HTA was impressed by the professionalism shown by staff who work under the licence.

Report sent to DI for factual accuracy: 11 March 2011

Report returned from DI: 22 March 2011

Final report issued: 24 March 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 in place 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 3: 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. There are varying levels of 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.

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.