Site visit inspection report on performance against HTA quality standards
University of Nottingham Medical School
HTA licensing number 12265

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

25 - 26 May 2011

Executive Summary

A site visit inspection of University of Nottingham Medical School (the establishment) was carried out by the HTA on 25 and 26 May 2011.

The establishment was found to have met all of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Advice has been provided to the establishment for their consideration. Specific examples of strengths and good practices are included in the concluding comments section of the report.

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.

All 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

The University of Nottingham Medical School is licensed for the storage of relevant material for use in the scheduled purpose of research. The main licensed premises are the Queens Medical Centre, the hub. There are a further three premises, licensed as satellite sites: the Nottingham City Hospital Campus, the School of Graduate Entry Medicine and Health situated at the Royal Derby Hospital, and the Sutton Bonington Campus of the University of Nottingham. The inspection team were assured that no licensable activity is taking place at the Sutton Bonington satellite site and the licensing requirement for the site is under review, therefore this site was excluded from the inspection.

Each of the inspected sites had several different research groups carrying out research within different fields, using fixed or frozen tissue samples. The samples were mostly procured from living patients for research projects with recognised ethical approval, or from volunteers who were consented to take part in research projects. The university has a written agreement with Nottingham University Hospitals NHS Trust to ensure that valid consent has been given for samples from the deceased.

A routine inspection of the establishment was carried out, comprising a visual inspection of the premises, interviews with members of staff, review of documentation and audit trails. Due to the many different research groups across the hub and satellite sites, multiple audit trails were carried out to ensure the tissue storage details were correct for the tissue being stored and where possible the consent documentation was also reviewed. In the majority of cases, no anomalies were found although some minor errors in the recorded storage location were identified. In one instance an incorrect freezer number had been recorded for a complete batch of tissues due to moving the samples from one freezer to another without updating the location. There was also a minor discrepancy noted in the sample labels for one project, where the letters ‘AJ’ had been transcribed incorrectly as ‘AS’.

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).

All applicable HTA standards were found to be met during the site-visit inspection of the University of Nottingham Medical School.

Advice

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

No.	Standard	Advice
1.	C1, C2, C3	Valid consent is obtained by relevant research groups although some groups have rather more developed systems and documented procedures than others. The DI is advised to continue to develop consent procedures in all research groups to the same high standards. Consent training is undertaken by all staff involved in obtaining consent; however the DI is advised to ensure that up-to-date training records are maintained across all the research groups.
2.	GQ6, GQ2	The audit trail conducted by the inspection team revealed a small number of minor anomalies which could be quickly rectified by the relevant staff. In spite of these, the samples were located within a short time frame. The establishment is advised to conduct further sample audits in these areas to assure themselves that they have full traceability of their samples.
3.	PFE3	Approximately 40 freezers were reviewed in the course of the inspection. All of the freezers had contact details and action to take in the event of freezer failure, with one exception. The DI is advised to display these details on the one remaining freezer.
4.	D1	The procedure for disposal is documented as a Standard Operating Procedure (SOP). However some staff were a little unclear of the appropriate way to dispose of slides sensitively in accordance with the Human Tissue Act 2004. The DI is advised to ask all relevant staff to read and implement the disposal SOP.

Concluding comments

During the inspection of the University of Nottingham Medical School, several areas of good practice were noted. The DI and Quality Manager have put in place a strong governance system. Each research group storing relevant material is provided with two 'Human Tissue Act' folders. The first contains establishment wide SOPs, training records and audit records. The second is intended for each research group to add their own local documents and SOPs. This system ensures a consistent approach in governance and quality systems throughout all the research groups across all sites. Each research group carries out annual audits on their own work area in advance of a systematic audit completed by the DI and Quality Manager where the results of local audits and any subsequent corrective actions are also reviewed. In addition, the face to face audit provides an opportunity for the DI to discuss issues with the Persons Designated (PDs) and share learning from other groups who may have more developed systems.

The premises are in all cases maintained to a high standard of cleanliness and relevant maintenance contracts for freezers are in place. All critical freezers have a temperature probe which connects to an autodialer which alerts staff if the temperature of a freezer is out of the specified range. The majority of the -80°C freezers have CO_2 backup supplies and if these precautionary measures are not in place a risk assessment has been completed for the risk of loss of the integrity of samples.

There are a number of examples of good practice related to consent. Consent is obtained only by a small number of groups, as much of the relevant material is received from third parties with whom the establishment have agreements to ensure valid consent is in place. Consent for a clinical procedure is documented on a standardised form, which includes that

tissue may also be used for research. In addition, the research groups ask patients to complete a research consent form, which provides more information about the research and gives the consenter greater awareness of how the tissue may be used. In general, broad consent is obtained so that the tissue may be used within a number of different research projects. Where tissues may be sent abroad as part of the research project or undergo genetic analysis, this is made clear before consent is obtained. Where appropriate, the research projects have been approved by either a local University ethics group or a recognised NHS research ethics committee, which provides assurance that the tissue is procured and utilised in an appropriate way and assists with achieving high standards of consent documentation and systems to maintain traceability of the samples.

Although a few minor discrepancies were identified as part of the audit trail, these were minimal in relation to the large number of samples audited during the course of the inspection and the DI has been provided advice in this area. No shortfalls were identified during the inspection. The establishment has been provided with advice to help staff to continue to raise standards.

Report sent to DI for factual accuracy: 15 June 2011

Report returned from DI: 29 June 2011

Final report issued: 25 July 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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.