**Site visit inspection report on performance against HTA quality standards**
**Durham University**
**HTA licensing number 12382**

**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**

**8 – 9 June 2011**

## Executive Summary

A site-visit inspection of Durham University (the establishment) was carried out by the HTA on 8 – 9 June 2011.

The establishment was found to meet many of the HTA standards across the four areas of: consent (C); governance and quality systems (GQS); premises, facilities and equipment (PFE); and disposal (D). One major shortfall was found in relation to the C1 standard. This was as a result of an accumulation of several minor shortfalls against this standard. Minor shortfalls were found in relation to the C, GQS and PFE standards; pages 3 – 5 give further details. Examples of strengths and robust practice are included in the concluding comments section of the report.

The HTA found the Designated Individual, the Licence Holder (Durham University), 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

This report refers to the activities carried out by Durham University (the establishment). This was the first site-visit inspection of the establishment by the HTA since it was issued an HTA licence in 2007.

The HTA licence at Durham University covers the Durham Campus (the hub) and the Queen's Campus, Stockton-on-Tees (the satellite). Relevant material is stored for the scheduled purposes of research in connection with disorders, or the functioning, of the human body (research) and education or training in relation to human health (education). Tissue collections are found in the Departments of Biological and Biomedical Sciences (stored for research and education), Psychology (research), Anthropology (research) and Physics (research). In total, the establishment stores approximately 7500 samples for these two scheduled purposes; 3500 samples are for education and 4000 samples are for research. All tissue collections are stored under secure conditions.

All research samples are from living donors. They include frozen samples (skin biopsies, tumour biopsies, saliva samples, whole blood samples) stored in -20°C and -80°C freezers, chilled samples of polymer-embedded tooth fragments in refrigerated storage, paraffin-embedded tissue blocks (pancreatic/stomach samples, skin biopsies, tumour tissue) and tissue sections on slides (skin and tumour biopsies). Approximately one-third (1500) of the research samples are under current NHS Research Ethics Committee (REC) approval. These are samples procured at local Trusts and transported to the establishment. Storage of these samples is exempt from HTA licensing. Some of the remaining samples are under Durham University Departmental Ethics Committee approval; these are samples which have been obtained on site or have been imported from overseas sources – Bangladesh and Gambia. Storage of these samples falls under the HTA licence. A further set of samples was originally stored under NHS REC approval and this has now expired. Storage of these samples falls under the HTA licence.

Education samples are from both living and deceased donors. They are all existing holdings and include formalin-fixed tissue, blocks and slides of normal tissue (thyroid, skin, tooth, bone, nerve fibres, cardiac muscle, prostate, adult and foetal skulls, skeleton hands, and an incomplete skeleton) and tumour tissue. Storage of the samples from the deceased donors falls under the HTA licence.

The site-visit inspection included the visual inspection of five tissue collections. Interviews were conducted with the Designated Individual, the Director of the Research Office (who is the Corporate Licence Holder Contact, CLHC) and seven Persons Designated.

A vertical traceability audit of material in each tissue collection was carried out from tissue records of receipt to storage and disposal (where applicable). Three randomly chosen samples were audited from each collection. All stored material was fully traceable.

## 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).

**Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed.** A template for this purpose is provided as a separate Word document.

## HTA standards not met

### Consent

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| 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. | There is inconsistency in the consenting process: | **Major** (as a result of the accumulation of the following minor shortfalls): |
| | - There is no Standard Operating Procedure (SOP) for acquiring consent in accordance with the Human Tissue Act 2004 (HT Act) and the HTA's Code of Practice on Consent (Code 1). | **Minor** |
| | - Consent forms vary from one University Department to another. Some of the consent forms did not comply with the HT Act and the Code of Practice on Consent. | **Minor** |
| | - Consent forms for some studies are included in the records whereas for other studies they are not. | **Minor** |
| C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent. | There is no evidence of training of staff involved in seeking consent for studies covered by University/Departmental Ethics Committee approval. | **Minor** |

**Governance and Quality**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process. | The Quality Management System (QMS) is underdeveloped with evidence of inconsistency in its implementation across licensable activities:<br>- SOPs cover some, but not all, of the activities under the licence.<br>- The format of SOPs varies between different research groups. Lack of centralisation has led to some duplication.<br>- Not all SOPs have been reviewed. | **Minor**<br>**Minor**<br>**Minor** |
| GQ2 There is a documented system of quality management and audit. | Owing to lack of centralisation there is no assurance that the most up-to-date SOPs are being used, and some SOPs are past their review date.<br>The audit programme is underdeveloped in that there is no planned schedule of audits encompassing all areas and aspects of licensable activities. The schedule of audits should supplement the development of a more structured framework of SOPs under the Human Tissue Governance Policy Master File **(see Advice 5)**. | **Minor**<br>**Minor** |
| GQ4 There is a systematic and planned approach to the management of records. | There is no regular audit of record content to check for completeness, legibility and accuracy. | **Minor** |
| GQ7 There are systems to ensure that all adverse events are investigated promptly. | The establishment has provided a good example in practice of handling a serious adverse event, including a detailed corrective action plan, but there is no documented SOP for handling (serious) adverse events. | **Minor** |
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | There are Health and Safety risk assessments but there are no documented risk assessments for the procedures associated with licensable activities. | **Minor** |

**Premises, Facilities and Equipment**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| PFE2 Environmental controls are in place to avoid potential contamination. | Although they are cleaned regularly there are no documented cleaning and decontamination procedures for the fridges and freezers used to store relevant material. | **Minor** |
| PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records. | Temperature monitoring of critical storage areas is inconsistent. Some research groups monitor their fridges/freezers on a continuous basis whereas other groups do not monitor them at all. | **Minor** |
| PFE4 Systems are in place to protect the quality and integrity of body parts, tissues and cells during transport and delivery to a destination. | Staff in the establishment occasionally use Departmental vehicles for obtaining samples from Trusts. This method of transport has not been risk assessed. | **Minor** |

**Advice**

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C1 | For some NHS REC-approved studies there is no written assurance (via Materials Transfer Agreements) from Trusts that consent has been obtained in accordance with the HT Act and the Code of Practice on Consent. The DI is advised to obtain such assurance. |
| 2. | C1 | For the consent and governance implications underlying imported tissue the DI is referred to the HTA Code of Practice on 'Import and export of human bodies, body parts and tissue (Code 8, paragraphs 29-35):<br><br>http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code8importandexport.cfm |
| 3. | C1 | The DI is advised to ensure that all University consent forms have reference to the Departmental Ethics Committee approved study code. |
| 4. | C3 | For NHS REC-approved studies there is no written assurance (via MTAs) from Trusts that consent has been obtained by trained individuals. The DI is advised to obtain such assurance. |
| 5. | GQ1 | The establishment has created a detailed 'Human Tissue Governance Policy Master File' (see Concluding Comments). This sets out the essential requirements of the QMS but needs to be fully and formally implemented. |
| 6. | GQ1 | Although a team of HTA advisors to the DI has been identified and placed on the establishment's organisational chart (which includes PDs, the CLHC and the University Biological Safety Advisor) there have currently been no formal meetings of this group to implement action. The DI is advised to initiate this. |
| 7. | GQ2, 4 | The DI is advised to divide the audit schedule into small increments, carried out by different team members, which builds on and expands the ad hoc audits which have been carried out to date. This could cover SOPs of record completeness and product receipt, storage, transportation and disposal. |
| 8. | GQ3 | Although some staff have received training in the importance of handling human tissue the DI is advised to update this training to all staff working under the licence.<br><br>The DI may wish to consider using the HTA E-learning package:<br><br>http://www.hta.gov.uk/trainingandconferences/onlinetraining/trainingfordesignatedindividuals.cfm<br><br>or the MRC Research and Human Tissue Legislation E-learning Module, part of the MRC Data and Tissues Toolkit, when developing such regulatory training for staff:<br><br>http://www.rsclearn.mrc.ac.uk/<br><br>The MRC module and toolkit were developed with input from the HTA. |

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|---|---|---|
| 9. | GQ4 | There is no centralised, backed up, register of all tissue held by the establishment which is available to the DI. Use of such a tissue register would provide information on when tissue stored under NHS REC approval is approaching its expiry date. The DI is advised to create this. |
| 10. | GQ6 | To facilitate product traceability the DI may wish to consider adopting a unique product identifier coding system. |
| 11. | PFE3 | The DI is advised to ensure that all human tissue in fridges and freezers is clearly labelled and is stored separately from other material, such as laboratory reagents and animal tissue. |
| 12. | PFE3 | The DI is advised to risk assess all the fridge and freezer storage facilities used. |

**Concluding comments**

The HTA is satisfied that the practices undertaken under the licence are suitable. In addition, the HTA observed some areas of good practice, including the following:

- The creation of a detailed 'Human Tissue Governance Policy Master File', which includes templates for SOPs, risk assessments, MTAs, consent forms and sample logs. This has been placed on the University's website and was released following the University's 'HTA Compliance Report - Management Assurance Review'.
- A secure contingency storage facility.

The HTA is satisfied that the premises are suitable. They are well maintained, are monitored, and are fit-for-purpose.

The HTA is satisfied that the establishment is suitable to be 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.

**Report sent to DI for factual accuracy: 29 June 2011**

**Report returned from DI: 13 July 2011**

**Final report issued: 5 August 2011**

**Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 11 September 2012**

## 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

| Consent standards |
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| **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<br>• Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose<br>• 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<br>• 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<br>• 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<br>• Agreements with third parties contain appropriate information<br>• Independent interpreters are available when appropriate<br>• Information is available in suitable formats, appropriate to the situation<br>• 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<br>• Evidence of suitable training of staff involved in seeking consent<br>• Records demonstrate up-to-date staff training<br>• Competency is assessed and maintained |

| Governance and quality system standards |
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| **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<br>• Appropriate risk management systems are in place<br>• Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes<br>• 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).<br>• Schedule of audits<br>• 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<br>• Orientation and induction programmes<br>• Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training<br>• Training and reference manuals<br>• 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<br>• Regular audit of record content to check for completeness, legibility and accuracy<br>• Back-up / recovery facility in the event of loss of records<br>• 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<br>• 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<br>• 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<br>• 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.