Site visit inspection report on compliance with HTA minimum standards

The Walton Centre NHS Foundation Trust

HTA licensing number 12030

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**

4 December 2013

Summary of inspection findings

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

Although the HTA found that The Walton Centre NHS Foundation Trust (the establishment) had met the majority of the HTA standards, shortfalls were found, in relation to consent documentation.

In preparing for this inspection, the establishment had identified shortcomings in the consent documentation used in relation to non-coronial (consented) post-mortem examinations, and the supporting procedures. These were confirmed by the HTA, following inspection, as minor shortfalls.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The licensed establishment is the Walton Centre NHS Foundation Trust, which incorporates a Clinical Trials Unit and is the only specialist neurosciences NHS Trust within the UK.

Establishment staff are involved in approximately 130 different neurology or neuroscience based research projects, locally, nationally and internationally, either within the establishment itself or in collaboration with researchers at other centres.

The establishment has set up a Research Tissue Bank with National Research Ethics Service approval, and this became operational early in 2011, holding de-identified brain tumour samples which the establishment can release to other researchers.

Consent for storage of samples from living donors for use in research, or other scheduled purposes, is obtained by trained research staff at the establishment.

Tissue from deceased patients is received following post-mortem examination (PME), either from other HTA-licensed post mortem establishments or following PME carried out by the establishment's pathologists at a neighbouring NHS Trust. The establishment's staff carry out coronial PME, and receive tissues for examination, from seven local coronial districts.

In addition, tissues may be received following non-coronial (consented) PME. In most cases this activity falls under the control of Designated Individuals within other HTA-licensed establishments. However, rarely, establishment staff provide consent documentation,

including guidance on the post mortem procedure, to local general medical practitioners in order that they may seek consent for a post mortem examination.

Samples received at the establishment are accompanied by completed consent forms or, in the case of post mortem material, confirmation of relatives' wishes as to the retention, repatriation, or disposal of tissue samples following examination.

Each sample is given a unique identifier, which is then used to trace the sample and subsequent block and slides through the laboratory into storage or ultimate disposal. Where tissue is stored in the research tissue bank for release for research, it is also provided with a research number, which ensures that tissue released to researchers is de-identified.

Samples are stored within -80°C freezers, which are alarmed and monitored remotely, or as tissue blocks and slides within specific storage areas.

During the inspection, the HTA met with staff within the clinical research unit to discuss the nature of the samples held within the unit, and whether these samples fell under the licence. Advice has been provided to the DI regarding the samples within this unit.

This was the establishment's first HTA inspection and comprised a visual inspection of the storage facilities, review of documentation, including consent information, policy, procedural and other governance documentation, records of environmental monitoring, equipment maintenance records and records of staff training. Key members of staff were interviewed. In addition, an audit of traceability was carried out:

One set of blocks and slides in storage were audited against related electronic and paper records for: the presence of valid consent; details of the storage location, and; confirmation of the number of blocks and slides retained.

One set of frozen tissue samples was located, and the corresponding records reviewed, for presence of valid consent as well as details of the storage location and number of vials retained.

Documentation relating to two consented post mortem examinations was retrieved and the corresponding tissue samples located and verified.

One organ held in storage was located and the corresponding consent and other documentation reviewed.

In one case, there were minor discrepancies in the number of slides recorded as being stored, resulting from two additional re-cut slides not being recorded within the laboratory database.

For one hospital (consented) PME, the relevant consent form did not fully demonstrate that there was consent for retention of tissue samples for use for research.

In both cases, advice has been provided to the DI.

Except as detailed above, no discrepancies were identified.

Inspection findings

The HTA found the DI and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

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.	The consent form supplied by the establishment to those taking consent for non-coronial post mortem examinations, who are typically clinical staff at the neighbouring NHS Trust and local general medical practitioners, is outdated and does not fully reflect the terms of the Human Tissue Act 2004. In addition the “Guide to the Post Mortem procedure” contains information which suggests that tissue samples may be retained indefinitely, without the need for consent and does not clarify that retention must be for scheduled purposes. In choosing to classify this as a minor shortfall, the HTA has taken into account that a risk assessment of the consent procedure carried out by the establishment in advance of the inspection had identified these issues and revised documentation has been drafted, but not yet issued.	**Minor**

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	When the establishment supplies consent forms and supporting documentation to local general medical practitioners or other clinicians who wish a post mortem examination to be carried out, there is no way to ensure that those seeking consent in such circumstances fully understand the implications and essential requirements of taking consent. There are no formal procedures or protocols in place requiring that those seeking consent are informed of the implications and requirements by establishment staff. In choosing to classify this shortfall as minor, the HTA has taken into account that consent for non-coronial post mortem examinations is generally sought by trained staff at nearby HTA-licensed establishments, and it is rare for consent to be sought in the circumstances detailed above. The HTA also notes that staff at the establishment have provided guidance to those seeking consent in the past, on an informal basis, and that the DI has identified this as an issue which needs addressed. Furthermore, the HTA notes the DI has suggested that a protocol or procedure is implemented which requires those seeking consent to contact the establishment in advance of the consenting procedure in order that trained establishment staff may clarify the implications and essential requirements, but this has not yet been drafted.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to review the procedures relating to receipt of tissues and accompanying consent forms. In particular, this should ensure that there a protocol to deal with the situation where there is any ambiguity or lack of clarity of instructions for dealing with tissues retained following a consented post mortem, in order to ensure that there is no possibility of tissues being retained for use for research without appropriate consent.
2.	GQ1, GQ4	The DI is advised to remind staff entering details of the number of slides produced from tissue blocks onto the Laboratory Information Management System to record those cases where re-cut slides are produced, in order to

		ensure accuracy of records. This will help to ensure that, where instructions are received to dispose of retained tissue samples, staff are able to determine the number of blocks and slides to be located and disposed of.
3.	GQ8	The DI is advised to record the review of risk assessments on an annual basis. Where risks associated with procedures have not changed, this review could be recorded as a simple statement of that fact. Where procedures or risks have changed, risk assessments should be updated and the update recorded. The HTA notes that risk assessments are updated on any change of practice and are currently reviewed biennially but a more regular review will help identify areas where service could be improved.
4.	N/A	The DI is advised to determine whether all tissue samples held within the Clinical Research Unit are being held for specific research projects approved by a recognised research ethics committee (as they are understood to be) and therefore need not fall within the DI's responsibility. In the event that this is the case, the DI is advised to confirm this to the HTA in order that the records held by the HTA are correct, which will inform arrangements for any future inspections.

Concluding comments

The HTA saw various examples of good practice during the inspection. It uses a proprietary quality management system, accessible by all staff, to manage documentation, schedule audits and risk assessment and to record incidents and follow up actions.

Documentation appears to have been well considered and in particular the establishment has produced clear guidelines for staff and visitors outlining the conduct expected when in the establishment.

The procedures for transport and fixing of tissue samples procured during post mortem examination at the neighbouring trust mortuary have been well considered to minimise risk of loss of traceability and damage to samples retained.

The establishment has set up a comprehensive suite of risk assessments and audits, scheduled by the electronic quality management system.

The Trust's consent policy has a specific section relating to the Human Tissue Act 2004 and is clear with regard to the requirement of consent for storage for use for scheduled purposes.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the DI with respect to licensing arrangements, consent documentation, records of slide production and review of risk assessments.

The HTA requires that the DI addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 12 December 2013

Report returned from DI: 2 January 2014

Final report issued: 6 January 2014

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: 28 February 2014

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.