Site visit inspection report on compliance with HTA minimum standards

Addenbrooke's Hospital

HTA licensing number 12315

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**

9-10 March 2016

Summary of inspection findings

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

Addenbrooke's Hospital (the establishment) was found to have met all HTA standards.

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

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

Addenbrooke's Hospital ("the establishment") is licensed by the HTA under the Human Tissue Act 2004 (HT Act) for the storage of relevant material which has come from a human body for use for a scheduled purpose. The establishment has held a licence since July 2007 and was first inspected by the HTA on 22 and 23 April 2008. This report describes the second, routine, site visit inspection of the establishment. The timetable for the inspection was developed in consideration of previous inspection findings, compliance update information and discussions with the Designated Individual (DI).

The establishment is part of the Cambridge Biomedical Campus. The main tissue bank, the Human Research Tissue Bank (HTRB) is located in the Histopathology department of Addenbrooke's Hospital. The licence also covers several institutes on the campus; these include the Cambridge Institute for Medical Research and MRC Mitochondrial Biology Unit, the Hutchinson/MRC Research Centre, the Cambridge Bone Bank, the Cancer Research UK-Cambridge Institute, the Medical Research Department, the Peacock Group and the Dermatology department. The Strangeways Research Laboratories for Genetic Epidemiology is located off- site from the campus and operates as a satellite under the licence. At the time of inspection, the Medical Genetics department did not hold any material under the licence. For each of the premises there is a Person Designated (PD) responsible for the supervision of the activities under the licence.

The establishment also stores relevant material for use in projects which have received favourable opinion from recognised research ethics committees (RECs), which is therefore exempt from the licensing requirements of the HT Act. Currently, there are 772 REC - approved projects, using human tissue, listed with the Trust's Research and Development department. The DI is not aware of the type and number of tissues currently held under ethical approval or when REC approval is expected to cease for each project, (advice, item 2).

Samples are either stored in locked freezers, in liquid nitrogen tanks or ambient storage areas which have restricted access. Freezer temperatures and liquid nitrogen levels are continuously monitored and there are alarms and procedures to deal with temperature excursions or equipment failure.

Relevant material is occasionally distributed by the establishment under a material transfer agreement (MTA), *(*advice, item 3).

The establishment has commenced using an electronic tracking system to track tissue removed in theatre for research purposes. These samples are stored in the HTRB or under ethically approved projects within the campus. It is the intention of the Trust to extend the use of the electronic tracking system to support the management of human tissue for research more widely, (advice, item 4).

The site visit inspection included a visual inspection of tissue storage facilities at each of the institutes and the satellite laboratory. For each site, the electronic records were reviewed and the recorded storage location for two samples was verified against the exact sample location. In addition, the paper or electronic confirmation that consent was obtained was also reviewed. In all cases, no anomalies were noted. A review of documentation was undertaken and meetings were held with the DI, the Corporate Licence Holder contact, the Tissue Bank Manager and a research nurse. Documentation reviews and audit trails were carried out.

Inspection findings

The HTA found the DI and the current Corporate Licence Holder (CLH) to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ2	To avoid misleading potential donors, the DI is advised to amend the wording of the reference to the 'HTA Research Tissue Bank' from the patient information leaflet, "Human Research Tissue Bank - Donating tissue or cells for research."

2.	GQ4	The DI is advised to establish more formal links with the Trust's Research and Development department to improve : • Oversight, such that tissue is issued only to researchers listed as working on specific projects. • The DI's awareness of when REC approvals are due to expire, enabling arrangements to be put into place to store material under the HTA licence or dispose of material which is no longer under REC approval.
3.	GQ5	If human tissue is to be transferred, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example as part of a Material Transfer Agreement (MTA), should define how the human tissue is preserved any potential contamination risks associated with it and who is responsible for disposal, if applicable. The HTA does not specify or endorse any particular format for MTAs; a number of template agreements are publically available and can be adapted to suit individual circumstances. In using their own MTAs, the DI is advised to consider the need to maintain traceability, including the keeping of records of suitable disposal.
4.	GQ6	A project is underway to extend the electronic sample tracking system to track samples in the tissue bank. The DI is advised to ensure that additional capacity and resilience is built into the IT systems to address the immediate requirements and also allow for future expansion or addition of further tissue banks. The DI is also advised to ensure that staff have protected time to assist in the development and robust testing of the tracking system.
5.	GQ7	The DI is advised to send regular – for example, annual - survey requests to all researchers in order to capture information on current tissue collections, new collections and any completed studies. This will help to strengthen oversight of relevant material being stored under the licence.
6.	GQ7	The establishment manages its adverse events but the document, "Quality Manual for HTA Research and Post Mortems" mistakenly refers to the need to report serious adverse event and reactions (SAEARs) occurring within the Human Application sector to the HTA. There is currently no requirement for establishments licensed in the research sector (as is the case for this establishment) to report adverse incidents to the HTA; however, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.
7.	N/A	Cambridge Hospital NHS Trust holds several HTA licences The named CLH contact, apart from assisting in overseeing the research licence, is also responsible for a number of other HTA licences. The HTA was informed that the CLH contact left the Trust just after the inspection. The DI is advised to inform the HTA of the name of the new CLH contact as soon as possible. The establishment is advised that the CLH contact should be more senior than the DI in order to substitute the DI where necessary.

Concluding comments

The HTA saw several examples of good practice during this inspection. There was good evidence of team work even though the institutes were spread over the Addenbrooke's site. There are regular governance meetings including bi-annual meetings of all PDs. The DI and PD of the HTRB have good oversight of the many collections under the HTA licence and were able to interrogate the tissue database in the Dermatology department, even in the absence of the PD for that collection, and locate samples during the inspection. A report is generated every month for the HTRB which highlights any missing information. The pathway of tissue from theatre to research has been strengthened through the use of the electronic tracking system. Researchers cannot take tissue directly to their laboratory until the material is booked on the system and suitable consent has been confirmed. The Quality Manager has been given protected time to develop SOPs and allow other staff to provide input into documented procedures. During the inspection, the DI took up the HTA's invitation to contact a similar licensed establishment to obtain advice on developing an intranet page, with information and templates for researchers.

The HTA has assessed the establishment as suitable to be licensed for the activities specified. To improve practices, the DI has been given advice on a range of issues.

Report sent to DI for factual accuracy: 5 April 2016

Report returned from DI: 19 April 2016

Final report issued: 25 April 2016

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.