Site visit inspection report on performance against HTA quality standards
Institute of Child Health
HTA licensing number 12220

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 June 2011

Executive Summary

A site visit inspection of the Institute of Child Health (the institute) was carried out by the HTA on 9 June 2011

The institute was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. A shortfall was found in relation to governance and quality systems. There were several examples of strengths and good practice and these are included in the concluding comments section of the report.

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.

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

Background to the institute and description of inspection activities undertaken

The institute is involved in research to enhance understanding, diagnosis, therapy and prevention of childhood disease. The licensed activity of storage of relevant material for use for a scheduled purpose, in this case research, takes place within three collections of research tissue within the institute, the Human Developmental Biology Resource ("HDBR"), the Cardiac Archive and the Baby Biobank. Much of the tissue held by the institute falls outwith the licensing remit of the HTA because it is being stored for projects which have received ethical approval from a recognised research ethics committee (REC) but the systems used apply in all cases in each location. Similarly, much of the resource is in the form of existing holdings, which predate the Human Tissue Act 2004 ("HT Act") but where possible, consent records have been retained.

Tissue, in the form of products of conception, is presently received into the HDBR from a separate clinical unit with which the institute has a contractual agreement. A research technician, trained by HDBR staff with regard to obtaining consent, the Human Tissue Act 2004 and the HTA's codes of practice, informs patients on the nature of the research projects involved and, if they agree to participate, obtains informed consent. Tissue is retrieved in the operating theatre, where a member of the HDBR staff attends. The tissue is de-identified after the retrieval as confirmation that consent has been given for retention of tissue for research and the corresponding consent form stored in patient notes is passed to the operating theatre by text from the research technician, in a way so as not to provide patient details. The tissue, when retrieved, is placed within a numbered pot, with no other patient identifying details, and it is this number, and the date of retrieval, which identifies the tissue when received into the HDBR. Transport is by specialist courier, under the terms of a service level agreement.

As a result of the early de-identification of the tissue, the staff at the HDBR have no way of linking the tissue to an individual patient and the consent taker can similarly not link the patient to the sample after retrieval. It is explained to those giving consent, that the early de-identification of tissues means that withdrawal of consent for research can only practically take place up to the time of the tissue retrieval.

When received into the HDBR, either from the separate clinical site or from the sister HDBR site each pot containing tissue is given a unique, sequential, number and entered onto a database and, as tissue is prepared in various ways, may be entered onto other spreadsheets. Storage takes place in various locations, depending on the method of preparation of the tissue, in -80c freezers, in alcohol or as prepared slides.

The Cardiac Archive consists of in excess of 2500 samples, the vast majority of which are existing holdings. Tissue is received from various other originating licensed establishments following post mortem, into the mortuary of a neighbouring licensed establishment with which the institute has a service level agreement, having been donated for the purpose of research into cardiac disease, specialist clinical opinion and for teaching purposes. Consent is obtained by staff at the originating licensed establishments and copies of the signed consent forms are either sent in advance or accompany the tissues. On receipt, each sample is given a unique number, entered into a paper record and an electronic database and stored within a location which is entered against that record, ensuring traceability.

The Cardiac Archive staff check the form of consent to determine whether tissue is to be returned to the originating establishment for repatriation with the body of the deceased, and if this is the case, that return to the neighbouring licensed establishment for return to the originating establishment is again recorded in paper and electronic form.

Storage of the Cardiac Archive materials is in one secure location within the institute.

Existing holdings are held under the HTA licence in the same location as the Baby Biobank which is itself currently awaiting samples.The existing holdings comprise a small number of prepared slides and some storage vials which were previously held by a researcher for a project with ethical approval from a recognised REC, but for which that approval has expired. Accordingly they are now held in the location of the Baby Biobank, under the terms of the HTA licence pending an extension to ethics approval, and are located within one shelf of a minus 80°C freezer, their location being held within an electronic database, and corresponding paper record, administered by the Baby Biobank staff.

This routine, scheduled, inspection involved a visual inspection of the all storage locations for each of the three collections, document review of various documents including the quality manual, overarching institute and local collection policies and standard operating procedures, risk assessments and audit records.

In addition, an audit of traceability was carried out:

- Within the HDBR one pot of tissues was traced on the electronic database to the identified storage location. Also, slides located in one of the storage locations were traced back to the corresponding entries on the electronic databases and spreadsheets. There were slight difficulties encountered with regard to identifying full traceability and this has been recorded as a minor shortfall below.

- Within the Cardiac Archive, one sample was located and the corresponding electronic and paper records reviewed to determine both traceability and the existence of consent documentation. Further, one of the existing holdings was traced from the electronic record to its indicated location within the store. No discrepancies were identified.

- In the Baby Biobank, the tissues being held were reconciled with a print out from the electronic record of same. Again, no discrepancies were found.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Within the HDBR, records relating to stored tissues are held on the principal database and, as this does not have the full functionality required for the purposes of the HDBR, also on other specific spreadsheets. Where tissue has been separated into smaller aliquots, separate vials or multiple slides, there is not provision for easily recording this on these digital records resulting in a potential loss of traceability. Further, there is evidence that staff are not consistently following a defined procedure to ensure that, where donated tissues have been prepared into multiple forms, such as slides or vials, this is recorded against the unique identification number to allow for a robust method of ensuring traceability.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to consider periodic audit of the consent forms retained at the clinical unit where tissue is donated into the HDBR for research, to ensure that the consent forms retained reflect the information provided and recorded by the HDBR staff on the date of collection of donated tissue.
2.	GQ6	The DI is advised, if any changes to SOPs and subsequent training of staff are carried out as part of the addressing of the shortfall detailed, to periodically audit the completeness of any records relating to traceability and the compliance of staff with any SOP relating to the entering of data relating to that traceability.
3.	PFE4	The DI is advised to consider instituting a system by which the Cardiac Archive staff are advised of the receipt of material for repatriation by the licensed establishment which originally retrieved the tissues and sent same to the Cardiac Archive for study.

Concluding comments

The HTA noted that a great deal of work had been carried out by staff at the institute in preparation for the inspection, in particular with regard to cross-referencing documentation in

the quality management system to the HTA standards. This facilitated the document review carried out as part of the inspection.

Many examples of good practice were seen.

A great deal of attention had been paid to the methods of training those seeking consent from patients donating material for entry into the HDBR and the recording of that training.

The valuable contribution of tissues into the Cardiac Archive had been recognised by the creation of a letter of thanks, which clinicians could choose to pass to those consenting to donation, or their relatives, where appropriate. This letter also reiterates the right to withdraw consent if the donor wishes to do so.

Periodic audits of processes, records and storage have been carried out and it is as a result of these audits that the material now stored under licence in the Baby Biobank was identified.

The HTA saw examples of risk assessments of not only the premises, but also of the activities carried out under the HTA licence and it was apparent that a great deal of thought had been put into those risk assessments, with results having led to changes in practice.

Staff had identified the difficulties with regard to the use of the database and electronic spreadsheets to record traceability data and steps are in place to attempt to adapt the existing database to ensure it has the required functionality. However, the HTA also noted that the staff had attempted to mitigate any issues resulting from the complications arising from the recording of traceability records in various formats by carrying out regular audit and inventory of material.

The HTA also noted the comprehensive nature of the recording of storage temperatures of the minus 80°C freezers and the out-of-hours alarm arrangements and allied contingency plans, all intended to minimise the risk of loss of valuable research tissues.

It was apparent throughout the inspection that the DI had a great deal of contact and communication with staff working under the licence and that all involved were very aware of the requirements of the HT Act and the ethical principles affecting their work.

Report sent to DI for factual accuracy: 17 June 2011

Report returned from DI: 21 June 2011

Final report issued: 22 June 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.

Date: 26 September 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.