Site visit inspection report on compliance with HTA minimum standards

St James University Hospital NHS Trust

HTA licensing number 12352

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**

22-24 April 2013

Summary of inspection findings

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

St James University Hospital Trust 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

This report describes the first site visit inspection of St James University Hospital Trust between the 22-24 April 2013. St James University Hospital Trust stores human tissue in a hub and satellite arrangement with the University of Leeds and Chapel Allerton Hospital. Each research group has a Person Designated (PD), who has oversight of respective storage areas. A patient registration system is used to register all patients' consent for prospective

collection of human tissue. The consent record is linked to a research database which allows sample tracking by all users of human tissue.

The University of Leeds has one research tissue bank that is under NHS ethical approval. This is the Skeletal Tissues Research Tissue Bank located at the Leeds Dental Institute where teeth are collected from routine extractions. The teeth are stored in the fridge no more than two to three days before the teeth are made available to researchers who will extract stem cells for research within the scope of the Human Tissue Act 2004 (HT Act 2004). A Person Designated is responsible for the collection of the teeth from clinic, their subsequent storage and their release to researchers. The Dental Tissue Bank also stores existing holdings for the scheduled purpose of research; however, at the time of the site visit inspection, these had not yet been catalogued (see advice and guidance item GQ6). The University of Leeds also stores human tissue under four projects with specific ethical approval. For one study, spinal tissue is removed from cadavers stored under the establishment's Anatomy sector licence with appropriate consent . The spinal tissue is transferred to the research study under formal agreement between the DI named on the Anatomy sector licence and the DI named on the research sector licence.

A processing laboratory at the Chapel Allerton satellite site also stores blood for university-sponsored clinical trials with NHS ethical approval and MHRA clinical trial authorisation. The technicians and the PD in the processing laboratory are involved in early discussions with researchers wishing to store their tissue in the laboratory. The laboratory also transfers tissue to commercial companies during collaborations. The storage lab accommodates -30^{o}C, -80^{o}C and -150^{o}C freezers and a fridge for the storage of media. At the time of inspection, the PD had notified the inspection team of a freezer failure that occurred prior to the site visit inspection. The samples had all been appropriately moved to the contingency freezers and an inventory clearly defined to where all samples had been moved. The laboratory was storing existing holdings in a -80^{o}C freezer, the contents of which the PD was planning to catalogue for the intended storage for research pending ethical approval.

The St James University Hospital NHS Trust hub site stores a large collection of human tissue under the Leeds Breast Research Tissue Bank, Leeds NIHR Research Tissue Bank and Leeds Multidisciplinary Research Tissue Bank. The Leeds Breast Research Tissue Bank stores blood from breast cancer patients and have recently started to receive breast biopsies. Blocks and slides for diagnostic purposes are stored for research purposes and have been catalogued appropriately. All of the research tissue banks have NHS ethical approval. The Leeds Multidisciplinary Research Tissue Bank holds several types of human tissue, including neuro-oncological, ovarian, urothelial, kidney and colorectal. The tissue for the Leeds NIHR Research Tissue Bank is 'mirror-banked' (i.e. duplicated) in separate -80^{o}C freezers, on site. The Leeds NIHR Research Tissue Bank receives urine and blood from tissue collection centres. The urine and blood that is received is processed and rendered acellular before it is stored.The buffy coat is stored for research purposes and does fall within the licensing remit of the HTA.

The inspection comprised a visual tour of storage locations at each site, traceability audits, document review and interviews with persons designated and other key members of staff working under the licence. All storage areas are temperature-monitored by appropriate systems that auto-dial designated members of staff in the event of freezer alarms being activated. Traceability audit trails of several tissue samples from the different research tissue banks were conducted. Both forward and reverse audits were carried out, from storage location to the electronic records and then from the electronic records to the storage location. The audit trail also included tissue samples transported from the establishment. For example, the storage location of a blood sample that had been sent from Chapel Allerton to St James University Hospital Trust for a specific project was recorded on the tracking system and the original location was empty on visual inspection. Similarly, paperwork supporting the transportation of a frozen OCT embedded kidney tumour transported outside of the UK was also checked. Appropriate tissue transfer agreements were in place for any transfers taking place. No anomalies were found during the traceability audits and the electronic systems demonstrated appropriate consent was in place.

Inspection findings

The HTA found the Designated Individual 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.	C1	The establishment has robust consent procedures in place and although all of the consent standards have been met appropriately, the DI may want to review and amend the booking in form which is received with blood samples, to ensure that it is clear to the laboratory processing the blood sample that consent has been obtained. This will provide the reassurance to the DI and establishment staff that consent is being obtained before any tissue is being processed or stored.
2.	C2	The DI may want to review the Consent SOP to add clarity in relation to appropriate completion of the consent form by the donor. This is in light of a query raised by a member of staff responsible for the consent process for a particular research study. During the review of a batch of consent forms it was brought to the attention of the HTA Manager and DI that some donors had not printed their forename and surname. Instead the donors had placed an initial as opposed to the full first name, followed by the surname. This resulted in the DI and the HTA Manager being contacted for advice as to whether the consent was valid. Thus, the DI is advised to update the current SOP so that the consent taker ensures that the donor follows the documented procedure. This will also reduce any ambiguity or confusion caused by individuals that share initials and surnames.
3.	GQ2	The DI and the HTA Manager have engaged in auditing all human tissue storage areas; however, they have not planned a formal audit schedule. At the time of the inspection, the Audit SOP was in draft format and had not been finalised. The DI and HTA Manager have been in discussions on how to go about auditing respective storage areas as the types of research and volume of storage is variable. During the inspection, the DI was advised to consider using the 'HTA standard 13 audit of respective areas' as a risk tool to assist the DI in determining audit frequency. The DI may wish to consider the option of PDs auditing each other's respective storage areas. Furthermore, it is advised that all audits and CAPAs are documented.
4.	GQ6	*There are two pieces of advice in this section* 1. Chapel Allerton does not use the same traceability systems as the other sites. The DI recognises that the functionality of the system at this site is limited in relation to capturing traceability of human tissue that is transferred from Chapel Allerton to the hub site. The DI may wish to consider other methods to track tissue transferred

		outside of the laboratory, where the system does not allow capturing this information. 2. Existing holdings are stored for future use in research; however, at the time of the inspection, the dental existing holdings and the existing holdings stored in the laboratory at Chapel Allerton had not been catalogued. The DI is advised to ensure that these are catalogued if they are to be stored for a scheduled purpose such as research and, if not, they should be disposed of appropriately. Particular attention should be given to tissue samples that are have been divided into pieces, to ensure full traceability of all tissue.
5.	GQ8	The establishment has a comprehensive adverse event SOP which details the types of adverse events that could occur under the four groups of HTA licensing standards. Although the establishment has risk assessments in place that refer to risks relevant to non-compliances with the standards, the DI is advised to consider carrying out risk assessments against the adverse events listed in the SOP to strengthen this further. Furthermore, the DI should also consider risk-assessing current contingency arrangements in the event of freezer failure.
6.	PFE3	All sites demonstrated appropriate contingency arrangements; however it would be beneficial for each research PD to integrate details of their contingency arrangements into their SOP so that in the event of equipment failure, staff members are able to follow procedures to relocate samples in a timely manner.

Concluding comments

The establishment has worked hard to ensure oversight of human tissue storage and use across both the hub and satellite sites. The DI, HTA Manager and PDs have a good working relationship with strong communication. The governance of the licence is robust and appropriate systems are in place to ensure that researchers are aware of the HTA's regulatory requirements. The IT Department have worked closely with the DI to develop a patient registration system as well as research database. Once the patient is consented they are registered on the patient registration system and are then linked to the research database which ensures that the donors are anonymised for research purposes. The HTA Manager acts as the custodian of the patient registration system and the restricted access ensures system security at all times.

A number of examples of good practice were observed during the inspection. The patient registration system offers a function where delegated list of consent seekers for each

research group can be viewed. This restricts who can seek consent and ensures that only trained individuals can seek informed consent. The HTA Manager also holds a delegated list of consent seekers with their respective signatures which is referred to during consent audits. The DI has established a good practice procedure where patients being seen in a hospital clinic are requested to sign a 'consent to be approached' form in clinic. Therefore if a patient is seen in clinic by a clinician, they will ask the patient for consent to be approached by a research nurse. This ensures that only patients who are willing to be involved in research are approached.

Although hospital interpretors are readily used, the DI is also working towards ensuring that information sheets and consent forms are available in several languages. The establishment has developed a HTA training template presentation which covers all of the HT Act 2004, including research. This template is provided by the HTA Manager to all research PDs to support their training needs. The PDs are encouraged to use this standardised presentation as a consistent training approach across the sites.

Report sent to DI for factual accuracy: 8 May 2013

Report returned from DI: 21 May 2013

Final report issued: 11 June 2013

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.