Site visit inspection report on compliance with HTA minimum standards

King's College Hospital NHS Foundation Trust

HTA licensing number 12378

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**

15 November 2012

Summary of inspection findings

The Liver Research Tissue Bank (also known as the Liver Biobank) at King's College Hospital NHS Foundation Trust (the establishment) was found to have met the majority of HTA standards. However, one minor shortfall in relation to premises, facilities and equipment (PFE5) was identified. Staff working under the licence are unaware as to whether the alarm monitoring system for refrigeration units is routinely tested. This shortfall has been addressed by the establishment to the satisfaction of the HTA prior to the final report being issued.

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

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 Paragraph 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 Liver Research Tissue Bank at King's College Hospital (KCH) is located within the Institute of Liver Studies. The Tissue Bank currently holds over 3500 samples, including tissue from liver and hepato-biliary biopsies, resection and explant specimens, blood and urine. These samples have been obtained from patients seen during clinical consultation. As KCH is a specialist referral centre, many of these samples are from rare or uncommon liver disorders. Consent for use of relevant material for research purposes is usually obtained by the referring liver clinician or another member of the healthcare team.

The Tissue Bank has NRES Research approval (reference: 08/H0704/117). Currently, end-users of Tissue Bank samples and data are local academic research groups performing studies in both experimental medicine and clinical research. Applications to use banked samples are assessed by the KCH Liver Bio-Bank Management Committee constituted by members with scientific, clinical and ethical experience and expertise, together with lay representation.

The establishment also performs routine diagnostic pathology within the Institute. There is no post mortem material stored within the Institute.

The DI is a Consultant Intensivist and Hepatologist and also Director of Research & Development at King's College Hospital. The CLHC is the Associate Director of Governance and Assurance. The Person Designated (PD) is Laboratory Director for the Institute and has managerial responsibility for staff working under the licence (including the Bio-Bank Manager and Supervisor) for activities relating to tissues, blocks and slides.

The establishment has been licensed by the HTA since February 2007. This site visit, undertaken on 15th November 2012, was a routine first inspection, which also provided an opportunity for the HTA to review governance arrangements. The visit included a visual inspection of the premises (sample receipt areas, processing laboratories and storage facilities – freezer room and ambient storage for blocks and slides) and formal interviews with the Designated Individual, the Corporate Licence Holder Contact, the Person Designated and other staff working under the licence.

A traceability audit was carried out on five samples, including three examples of frozen tissue and two cases stored as paraffin-wax embedded blocks. Each audit trail included: review of evidence of receipt, consent documentation, storage and data entry onto the establishment's management information system. All tissue samples are labelled and electronically coded. The establishment currently maintains two inter-connected computerised information systems to trace samples. No anomalies or discrepancies were found on the selected examples during the traceability audits.

A document review of the establishment's policies and operational procedures was also conducted. This included review of storage request forms supporting information, audit schedules for 2011/12 and 2012/13, risk assessments, internal service level agreements and other contracts, and the quality manual.

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

HTA standards not met:

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE 5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	Although there is an alarm monitoring system for refrigeration and freezer units, this is not subject to routine testing. Biobank staff are unaware as to whether the alarm system is functional. *The establishment has submitted two updated standard operating procedures which detail routine alarm testing requirements. The HTA has reviewed and assessed this information as satisfactory to address this shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1	C1	Consent is obtained in accordance with HTA regulatory requirements. There is some variability in practice with regards to copies of consent paperwork kept within Tissue Bank records. The DI is advised that the existing SOP should be consistently followed to ensure that the hard copy of the consent form is present and held in the Tissue Bank and that signatures of both the consent-giver and healthcare professional (i.e. counter signatory) are legible.
2	C2	Information relating to the consent process is available. An updated consent information booklet which refers to, and describes, HTA requirements would be recommended at the next point of revision.
3	C3	It is recommended that refresher training is provided to staff involved in the consent-taking process at suitable intervals so that individuals both maintain and are kept abreast of regulatory requirements relating to consent.
4	GQ8	The establishment has a clear risk assessment (RA) process in place. The DI is advised to further extend RAs to include potential risks related to tissue loss, loss of tissue integrity and loss of traceability. Given the advice under standard C1, it would be important to define the risk of receiving tissue with incomplete or non-conforming consent documentation and actions to be taken in such circumstances.
5	PFE5	On-site engineers are available to provide ad-hoc repairs for existing freezer facilities. The DI is advised to consider making provision for on-going annual maintenance and routine servicing of critical equipment

6	D2	Although the site is recording the reason for disposal, the database does not display this field. The DI is advised to consider that any future system modifications include a field clearly displaying the reason for disposal. Additionally, as there is potential anticipated growth in demand for material from the tissue bank, the DI may wish to consider establishing a mechanism whereby an establishment receiving material for defined research purposes confirms to the tissue bank that remaining tissue has been appropriately disposed of once the project has ended.

Concluding comments

A number of strengths and good practices were identified. For example: the establishment has an ID tracking system with unique identification numbers generated at the level of individual frozen and paraffin wax-embedded tissue samples. This facilitates a robust chain of custody process. Tissue Bank staff undertake monthly audits to routinely check and update the inventory of retained material. Consent training is initially provided at clinical staff inductions and is supplemented by further training specific to consent requirements for material donated for the purposes of research. The establishment also has a robust governance framework in place with evidence of regular committee meetings which include matters relating to licensable activities. These meetings take place within established Trust governance structures, with clear reporting lines, and provide opportunities for staff engagement at both operational and strategic level, e.g. Liver Biobank Management Committee (at departmental level) and the Human Tissue Act Committee (at corporate level).

As highlighted above, there are some areas of practice that require improvement and the HTA has given advice to the DI with respect to these.

Before the draft inspection report was finalised, the establishment submitted revised SOPs for freezer breakdown and alarm testing within the Tissue Bank. This information has been assessed by the HTA as satisfactory to meet the identified shortfall. Consequently, there is no longer a need to complete a corrective and preventive action plan in this regard.

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 single shortfall identified during the inspection).

Report sent to DI for factual accuracy: 7 December 2012

Report returned from DI: 10 December 2012

Final report issued: 24 December 2012

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 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 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.

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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.