Site visit inspection report on compliance with HTA minimum standards

Royal Brompton and Harefield NHS Trust

HTA licensing number 12388

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 – 17 October, 2012

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.

Royal Brompton and Harefield NHS Trust (the establishment) was found to have met all HTA standards.

This was the establishment's first HTA inspection against its research licence. 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 establishment stores relevant material for research under a hub and satellite arrangement. The governance structure encompasses two biobanks and a pathology diagnostic archive, all with generic ethics approval, a number of research groups at the Royal Brompton Hospital (the hub), and research storage areas at four satellites including the Harefield site, covering Harefield Hospital and the Heart Science Centre, and three Imperial College Faculty of Medicine sites, namely: the Emmanuel Kaye, the Guy Scadding and the Sir Alexander Fleming Buildings.

Research groups at all sites may either store tissue from a biobank, with separate ethical approval, or under the licence. All material is treated by the establishment as falling within the tissue governance structure, to capture instances where material is stored, even when specific ethical approval has lapsed.

This was the first routine inspection including interviews with staff, document review and visual inspections of storage areas based across all sites. At the hub the visual inspection covered:

- two ethically approved biobanks:
    - cardiovascular biomedical research unit (BRU); and
    - respiratory BRU;
- histopathology diagnostic archive, with ethics approval; and
- two randomly selected research groups, holding tissue for ethically approved projects.

Several research groups were selected from the Imperial College sites for a visual inspection, specifically two at the Emmanuel Kaye Building, two at the Guy Scadding Building and one at the Sir Alexander Fleming Building.

Samples from one storage area at Harefield were included in the inspection. Harefield holds a static collection of cardiac transplant tissue. The establishment recently reviewed its processes for procuring and accessing tissue from this collection. Consequently, it submitted an amendment to update the cardiovascular biobank's ethics approval, to include this collection. Part of the establishment's ethically approved histopathology diagnostic archive is also held at Harefield.

A number of traceability audits were completed on samples across all areas, during the visual inspections. Samples were traced from the establishment's IT system to the -80 and -20°C freezers, liquid nitrogen tanks, and in one case, to a 37°C incubator. Original consent forms were traced for each sample. A number of samples were traced from the relevant storage area to the establishment's IT system. The diagnostic archive does not use the establishment's general IT system, and samples at the Royal Brompton were traced from a spreadsheet to the refrigerator in the histopathology laboratory. The majority of traceability audits did not reveal discrepancies; however a minority of traceability audits revealed mislabelling or misrecording of information. All discrepancies found were explained. Audits were also used by several areas to manage holdings and there was generally a strong awareness of the procedures in place to manage any anomalies (see Advice on GQ6).

Inspection findings

The HTA found the Designated Individual and the Licence Holder 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 and C2	The DI is advised to consider opportunities for greater harmonisation, particularly between BRUs, to increase the sharing of good practice across the biobanks. For instance, while consent forms were all traceable, there was inconsistency across BRUs in how patients indicate consent to an option on the form, for example either, ticking, crossing, initialling or circling to indicate consent, or crossing or leaving sections blank when a patient did not wish to consent to a particular section on the form. The DI may wish to consider an establishment-wide SOP on completing consent forms. All the respiratory BRU patient data forms, including fields for consent were completed correctly in line with practices, however some of the sections labelled "please complete all fields" were not completed. The DI is advised to further consider the reasons for incomplete forms, for example, by either reviewing the wording of the form or communicating to staff about the need to complete the section.
2.	GQ2, GQ4 and GQ6	A range of audits had been completed by the establishment, including traceability audits of samples stored against the establishment's IT system, records and consent documentation. While staff verbally confirmed actions arising from audits were all completed, the DI is advised to ensure all follow up actions and completion of follow up actions are clearly and consistently documented across all areas, to maximise benefits gained through investing resources in conducting audits.
3.	GQ6	The establishment's current IT system is effective in maintaining traceability of samples, although the establishment has identified potential areas for improvement. For example, the pathology diagnostic audit tracks its tissue blocks and slides using an Excel spreadsheet. One traceability audit was completed on tissue microarray blocks from the archive held on the hub site. Although the tissue microarray blocks were fully traceable, the number of tissue microarray blocks was not recorded on the spreadsheet used to record blocks in the diagnostic archive. Staff advised the spreadsheet for the diagnostic archive will be used until a more suitable tracking system is implemented for the site, however, in the interim, the DI is advised to record the number of blocks for tissue microarrays, check on general recording of block numbers for other types of blocks held and more generally, continue on-going work toward developing specifications for the next generation of IT system.
4.	GQ6	Two of the research groups visited at Imperial College store existing holdings, collected before the commencement of the Human Tissue Act 2004. Both collections are stored separately from other material and items are traceable to existing records. The DI is advised to review the storage arrangements for relevant archived collections, including the need for inventories of samples held under the licence. The DI is also advised to consider risk assessing the continued storage of existing holdings.
5.	GQ8 and PFE1	A range of risk assessments were completed by the establishment, including assessment of premises and assessment of all licensable activity. While staff confirmed actions in risk assessments were all completed, the DI is advised to ensure all follow up actions and completion of follow up actions are clearly and consistently documented across all areas, to maximise benefits gained through time and effort invested in conducting risk assessments.

6.	PFE3	All storage areas viewed were monitored and secure and human tissue stored under the licence was separated from other material. Some of the areas also clearly mark freezers as containing human tissue. The DI is advised to review signage in storage areas, for example including alarm set-points for temperature ranges on freezer signs, to improve ease of temperature monitoring, and review the marking of freezers, boxes and / or drawers to clearly indicate contents contain human tissue.

Concluding comments

A number of examples of good practice were observed during the inspection. The establishment is committed to meeting HTA standards through its tissue governance system, supported by a dedicated tissue governance manager. Establishment staff consistently identify potential areas for improvement, through a schedule of audits, a range of risk assessments and via discussion and dissemination of information, through a wide network of governance meetings.

The establishment uses its strong system of internal checks and communication links to effect changes to working practices, such as, amending pathology consent forms to clearly highlight consent for research and reviewing governance around the static cardiac transplant collection at Harefield.

The establishment has a good approach to consent and training. All original consent forms were easily traced from samples and all staff working with relevant material complete MRC e-learning modules as part of internal training requirements.

A specific example of good practice includes the Cardiovascular BRU's approach to training and consent. The team held a training day where each person was allocated an SOP to present. The SOPs were discussed by the group during training to ensure SOPs matched actual practices. The Cardiac BRU also uses a spreadsheet to track patients who have specified "no consent" when approached by staff to avoid re-contacting them. This approach has been identified as particularly appropriate to the Cardiac BRU's consent processes.

The HTA has given advice to the Designated Individual with respect to consent documentation, traceability, risk-assessments and signage.

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

Report sent to DI for factual accuracy: 6 November 2012

Report returned from DI: 20 November 2012

Final report issued: 6 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.

   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 preventive 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 preventive actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventive 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 preventive 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.