Site visit inspection report on compliance with HTA licensing standards

Papworth Hospital

HTA licensing number 12212

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**

06 March 2018

Summary of inspection findings

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

Although the HTA found that Papworth Hospital (the establishment) had met the majority of the HTA's standards, one minor shortfall was found in relation to consent training. The DI has been given some advice relating to consent, governance and quality systems and premises, facilities and equipment. Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to licensable activities carried out at Papworth Hospital (the establishment). The establishment is licensed for the storage of relevant material that has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use for the scheduled purpose of 'research in connection with disorders, or functioning, of the human body'. The establishment has been licensed since June 2007 and this was the second routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The establishment stores the majority of samples in the ethically approved Papworth Hospital Research Tissue Bank (RTB) (REC reference 08/H0304/56+5) which facilitates cardiothoracic research. The establishment also stores a collection of samples temporarily for the ethically approved Mesobank RTB (REC reference 13/EE/0169) which facilitates mesothelioma research.

Papworth Hospital RTB

Samples held in the Papworth Hospital RTB are mainly from the living; however, there are a small number of samples from deceased donors upon specific request from researchers. Relevant material is collected, processed and stored on site and includes tissue, whole blood and processed blood components. Approximately 80,000 samples are currently stored in the RTB, either frozen at -80°C or fixed in blocks and slides at room temperature.

All freezer areas are secured and located in designated laboratory areas with swipe card and/ or key code access. All freezers are fitted with automated alarms that are triggered by deviations from the set acceptable temperature ranges. Once temperatures go out of range, an external monitoring service alerts relevant members of staff by phone, 24 hours-a-day. The alarm system is not routinely tested (see *Advice*, item 4). All freezers are subject to annual servicing and, in the event of a power failure, are connected to a back-up generator. The establishment has contingency arrangements for all temperature-controlled storage.

All patients admitted to the hospital have the opportunity to donate material to the Papworth Hospital RTB. Clinicians and senior nursing staff are responsible for consenting patients. Consent seekers receive training regarding the requirements of the HT Act; however, consent training is a one-off event and no refresher training is provided (see shortfall against standard C2(b)). All potential donors are given an information sheet and time to ask questions before consent is sought (see *Advice*, items 1 and 2).

Each sample is given a unique tissue bank code. Once processed and aliquotted, each sample is stored in a labelled box. The establishment uses an electronic database to provide traceability of samples.

Mesobank RTB

The establishment stores a collection of samples temporarily for the Mesobank RTB. The Mesobank samples are collected from a number of recruiting hospitals around the UK and consent is obtained at the recruiting sites. Samples are sent from another HTA-licensed establishment (host establishment) to Papworth Hospital for processing and specialist analysis before being transported back to the host establishment. Samples are stored for approximately two months. There are agreements in place between the establishments and the RTB for the service.

As well as specialist analysis, Papworth Hospital is also a recruiting centre and therefore some samples are consented for and collected on-site. Consent is taken by clinical staff who are trained the same way as the clinicians for the Papworth Hospital RTB. Consent documentation is not held on site but accessible via a centralised study website.

Samples are from the living and include tissue, blood and pleural fluid. Each sample is given a unique identification number and stored in a labelled bag. All samples are stored in a designated -80°C freezer. Maintenance and temperature monitoring of the storage facility is the same as for the Papworth Hospital RTB samples. The establishment uses an electronic database and paper records to provide traceability of samples and the Mesobank RTB is responsible for transport between sites.

Description of inspection activities undertaken

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the DI, previous communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and interviews with a consent seeker, cell-bank coordinator and deputy pathology manager. The inspection also included a visual inspection of the areas where samples are stored under the licence and audits of sample traceability. Audits of the following, randomly-selected samples were conducted:

Papworth Hospital RTB

- Six samples from the -80°C freezer, from sample storage to consent.
- Three samples (from blocks/slide storage), from sample storage to consent.
- Two samples from consent withdrawal documentation to disposal records.

Mesobank RTB

- Two patients (ten samples) in freezer storage, from sample storage to documentation.

All samples were traceable with no discrepancies noted.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Consent training is given to staff on induction and addresses the requirements of the HT Act and HTA's Codes of Practice; however, this is given as a one-off event and there is no refresher training or other arrangements to ensure consent-seeking proficiency is maintained.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	Genetic testing is thoroughly explained in the patient information sheet for consent; it is not alluded to on the consent form. For clarity, the DI may wish to add a separate and specific clause to the consent form.
2.	C1(d)	The consent form and patient information sheet states that to withdraw consent the donor needs to write to the Papworth Research Tissue Bank. When the documents are next reviewed, the DI is advised to include the address of where correspondence should be sent to provide clarity to the donor.
3.	GQ1(a)	Some of the Mesobank SOPs reference the Human Tissue Act 2006. This should be corrected to reference the Human Tissue Act 2004.
4.	PFE2(c)	All relevant material is stored in temperature-monitored freezers that have external alarm and call-out systems. The DI is advised to challenge the alarm systems to ensure that when temperature deviations are detected the system operates successfully.
5.	PFE3(a)	The freezers are due to undergo annual servicing however; the contractor has delayed the visit. The DI is advised to ensure that this is carried out as soon as possible.
6.	N/A	The current HTA licence on display in the main foyer has details of the previous DI; this should be updated with the current licence issued.
7.	N/A	To increase the awareness of staff working in the laboratory, the DI is advised to label the Mesobank freezer to highlight that it contains human material.

8.	N/A	There is no Persons Designate (PD) overseeing activity for the Mesobank RTB. The DI is advised to add a relevant PD to the licence.

Concluding comments

This report outlines the second, routine HTA site visit inspection of Papworth Hospital. A number of strengths and areas of good practice were observed during the inspection, including:

- The establishment has developed a robust system for sample traceability, including thorough practices for when samples are transported to researchers and other HTA-licensed establishments.

- The small team of RTB staff that undertake key activities under the licence appeared committed and demonstrated a willingness to work together to ensure compliance with the HTA's licensing standards.

- Staff at the establishment demonstrated that they strive towards improvement of practices, and were open to the advice offered by the HTA during the inspection.

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

Report sent to DI for factual accuracy: 26 March 2018

Report returned from DI: 06 April 2018

Final report issued: 06 April 2018

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 and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report**.**

Date: 24 July 2018

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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.
d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.

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.