Site visit inspection report on compliance with HTA licensing standards

Salford Royal NHS Foundation Trust

HTA licensing number 12291

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**

13 & 14 February 2019

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.

The HTA found that although Salford Royal NHS Foundation Trust had met the majority of the HTA's standards, one minor shortfall was found relating to risk assessments.

The DI has also been given advice on a range of issues.

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 Salford Royal NHS Foundation Trust (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 November 2007 and was last inspected in November 2015. This report describes the third routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The establishment stores relevant material in three Research Tissue Banks (RTBs): Vascular Diseases Biorepository (09/H0906/14+5), Salford Respiratory Biobank (13/NW/0767) and the Manchester Brain Bank (09/H0906/52+5). There are also other collections stored in the Salford Biorepository facility by individual research groups. Samples include tissue (fixed and frozen), whole blood and processed blood components, cerebrospinal fluid (CSF) and saliva. The establishment also stores human samples for research projects that have project-specific approval from recognised research ethics committees (RECs). Although these are exempted from the licensing requirements of the HT Act, there is a robust system by which the Research and Innovation Department monitor when REC approval is coming to an end to ascertain when samples will be held under the authority of the HTA licence.

Relevant material is stored throughout the Clinical Sciences Building of Salford Royal Hospital at room temperature, -80˚C and in liquid nitrogen. The corridor that leads to the laboratories and storage areas is secured by a key pad. Only authorised personnel have access; visitors must be accompanied and are required to sign in and out at the entrance. The storage rooms off the main corridor are locked, providing further security, and the majority of the freezers storing relevant material are locked.

Samples stored at room temperature include a large collection of fixed tissue, stored in a designated, locked room and saliva samples stored in a locked cabinet.

The freezers are fitted with automated alarms that are triggered by deviations from the set acceptable temperature ranges. If temperatures go out of range, an external monitoring service alerts relevant members of staff by telephone, 24 hours a day and, in the event of a power failure, they are connected to a CO_2 back-up (see *Advice*, item 2). The alarm systems are routinely tested and are subject to maintenance and servicing contracts.

There is a liquid nitrogen tank that stores relevant material. It can only be accessed by trained personnel and has an alarm system that notifies members of staff if nitrogen levels are low. There is an empty vessel that can be used as contingency storage (see *Advice*, item 2).

For active projects, research nurses and/or personal investigators are responsible for seeking consent. Projects are approved by an ethics committee prior to the start of the study and all consent seekers are trained, with refresher training provided every three years. Consent is sought using project-specific consent forms that reflect the requirements of the HT Act and the HTA's Codes of Practice, and all participants are given a detailed information sheet relating to the research and process (see *Advice*, item 1).

Material is collected from Salford Royal Hospital and transported to the Clinical Sciences Building. Each research group uses electronic records to provide traceability of samples. Some groups maintain additional paper records of sample traceability. Samples are assigned a unique identification number by individual researchers, and these numbers are used to track sample receipt, storage, release for use in research and disposal (see *Advice*, item 6). Information about each collection is held in a HTA compliance file, maintained by the Person Designated (PD) responsible for that collection.

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 round table discussions with staff involved in consent seeking, quality management and sample management. The inspection also included a visual inspection of all the areas where samples are stored under the licence and audits of sample traceability. Audits of the following, randomly-selected samples were conducted:

- Six samples, from storage to traceability records to consent documentation, from the Manchester Brain Bank.
- Three samples, from consent documentation to traceability records to storage, from the Salford Respiratory Biobank.
- Five samples, from storage to traceability records, from the Peripheral Blood Lymphocyte archived collection.
- Two samples from individual research groups collections, from consent documentation to traceability records.

All samples were fully traceable. However, three consent forms were not completed as required by the establishment, being completed with ticks in the check boxes instead of initials (see *Advice*, item 1).

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

Standard	Inspection findings	Level of shortfall
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	Although procedural documents demonstrated that risks associated with practices and processes relating to licensed activities had been considered, documented risk assessments were missing in some areas. (see *Advice*, item 4)	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	During the HTA audits, although appropriate and valid consent had been obtained, three consent forms were completed with ticks in the check boxes instead of being initialled as per instructions. The DI may wish to consider revising the consent forms to make it clearer to the donor that initials are expected.
2.	GQ1(a)	Although all storage conditions are monitored, the 'storage of human tissue samples for research' SOP does not detail the monitoring and alarm arrangements that are in place. Furthermore, this SOP does not detail the contingency arrangements. The DI is advised to include these relevant processes in the document to increase staff awareness.
3.	GQ1(c)	Some documents were reviewed in 2015. The DI is advised to ensure that all controlled documents are reviewed every two years as per SOP.
4.	GQ6(a)	To address the minor shortfall against standard GQ6(a), the DI should ensure that documented risk assessments cover all of the practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. In particular, the DI should ensure that the following risks have been assessed: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • loss of human tissue; • sample loss of traceability; • transport of specimens to and from the establishment; and • incorrect disposal

		Further guidance on risk assessments of activities conducted under the licence can be found in the HTA's research sector licensing standards and guidance document, which is available on the HTA's website
5.	T1(a)	With the collections growing, a more streamlined approach to sample management, such as a unified database, may help to reduce the risks associated with loss of traceability.
6	T1(a)	Some samples are sub-aliquoted into multiple vials. Although the sample volumes and individual aliquot locations are recorded to provide traceability for each of the samples, the same identifier is used to label. The DI is advised to assign a unique code to each donation and each of the products associated with it.
7.	T2(a)	The 'disposal' SOP (HTA04) references the HTA's old Code of Practice on disposal, which was decommissioned. Although the new Code of Practice on Research is also mentioned, for clarity, the DI is advised to remove the outdated reference.
8.	T2(b)	Although disposal is carried out in accordance with the HTA's Codes of Practice, the 'disposal' SOP (HTA04) states that, following disposal, it is 'good practice' to record the date, method and reason for disposal. The DI is advised to reword this to highlight that it is a requirement (of standard T1(b)) to record these details.

Concluding comments

This report outlines the third, routine HTA site visit inspection of Salford Royal NHS Foundation Trust. A number of strengths and areas of good practice were observed during the inspection, including:

- There are a number of different RTBs working under the licence and the DI has developed a robust staff structure to ensure full oversight. Authority and responsibilities are shared between the DI, PDs and Research and Innovation Department.
- The DI has developed a set of training presentations that are targeted at different levels depending on the audience. There is a five minute talk that is used to increase hospital staff awareness of the HTA and a more detailed talk for staff working directly under the licence.
- The establishment has developed an audit schedule that includes local audits by the PDs responsible for the collections and audits from the Research and Innovation Department.
- 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.

Although the HTA found one minor shortfall, 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 shortfall identified during the inspection.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Report sent to DI for factual accuracy: 01 March 2019

Report returned from DI: 12 March 2019

Final report issued: 13 March 2019

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: 26 April 2019

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.